CONGRESSIONAL OVERSIGHT OF ADMINISTRATIVE AGENCIES

(FOOD AND DRUG ADMINISTRATION AND ENVIRONMENTAL PROTECTION AGENCY)

HEARINGS

BEFORE THE

SUBCOMMITTEE ON SEPARATION OF POWERS

OF THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

NINETY-FOURTH CONGRESS

FIRST SESSION

JULY 21 AND 23, 1975

Printed for the use of the Committee on the Judiciary

U.S. GOVERNMENT PRINTING OFFICE
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CONGRESSIONAL OVERSIGHT OF THE FOOD AND DRUG ADMINISTRATION

MONDAY, JULY 21, 1975

U.S. SENATE,
SUBCOMMITTEE ON SEPARATION OF POWERS,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The committee met, pursuant to notice, at 9:50 a.m., in room 2228, Dirksen Senate Office Building, Senator James Abourezk (chairman of the subcommittee) presiding.

Present: Senator Abourezk.

Also present: Irene Margolis, staff director; Carl Tobias, counsel.

Senator ABOUREZK. The Subcommittee on Separation of Powers hearing will come to order.

I will read a brief statement and then I will ask Dr. Schmidt to proceed.

OPENING STATEMENT OF SENATOR ABOUREZK

Today the Subcommittee on Separation of Powers of the Judiciary Committee commences 4 days of hearings to consider the role of certain administrative and regulatory agencies of the Federal Government. This first day of oversight hearings will be devoted to examination of the Food and Drug Administration, the second day to examination of the Environmental Protection Agency, and the concluding 2 days to examination of the Federal Reserve System.

These hearings are very much in keeping with a tradition established by the subcommittee of holding hearings which examine the function, role, and purpose of administrative and regulatory agencies.

While the subcommittee cannot ignore completely the substance of our policies with respect to either the food and drug industries, the environment, or monetary flow and economic stability, the major focus of these hearings will be administration of the various programs for which each agency has responsibility, the particular administrative procedures employed by each agency in implementing programs with emphasis on procedures used in formulating the rules, regulations, and orders promulgated by each agency, and the exercise of delegated power by each agency to ascertain whether it is within the bounds set by the Congress.

It is appropriate that we begin our oversight hearings with examination of the Food and Drug Administration. The FDA exercises broad power in several areas vital to the health and safety of all Americans. Regulation of food, drugs, and cosmetics—those things

that we put in and on our bodies—and the exceedingly complex and powerful food, drug, and cosmetic industries which distribute these products, places tremendous responsibility in and imposes very difficult duties on FDA.

Because of time constraints, I want to leave as much time as possible for the excellent witnesses we have scheduled for this hearing. Therefore, I will not read my prepared statement but will instead insert it in the hearing record at this point.

[The prepared statement of Senator Abourezk follows:]

PREPARED STATEMENT OF SENATOR JAMES ABOUREZK

Today the Subcommittee on Separation of Powers of the Judiciary Committee commences four days of hearings to consider the role of certain administrative and regulatory agencies of the Federal government. This first day of oversight hearings will be devoted to examination of the Food and Drug Administration, the second day to examination of the Environmental Protection Agency, and the concluding two days to examination of the Federal Reserve System.

These hearings are very much in keeping with a tradition established by the Subcommittee of holding hearings which examine the function, role, and purpose of administrative and regulatory agencies. Senator Ervin stated succinctly the Subcommittee's purpose in holding such hearings (hearing record before the Subcommittee on Separation of Powers, Congressional Oversight of Administrative Agencies, NLRB, Mar. 26, 1968, vol. 1, p. 1):

"The independent administrative agencies now constitute a fourth branch of the Federal Government—some have described them as the 'headless' fourth branch. In a relatively short time, they have come to have responsibility over major areas of public interest—transportation, public relations, communications, trade regulations, and finance, to mention only a few. Further, the administrative agencies are an innovation in the tripartite system, conceived by the Founding Fathers. The fact that they exercise a combination of legislative, executive and judicial powers, and so represent a major deviation from the separation of powers formula, is another reason for including them in our study."

While the Subcommittee cannot ignore completely the substance of our policies with respect to either the food and drug industries, the environment, or monetary flow and economic stability, the major focus of these hearings will be administration of the various programs for which each agency has responsibility, the particular administrative procedures employed by each agency in implementing programs with emphasis on procedures used in formulating the rules, regulations, and orders promulgated by each agency, and the exercise of delegated power by each agency to ascertain whether it is within the bounds set by the Congress.

The Subcommittee is particularly concerned with the impact of the programs administered by these agencies on those regulated. As Senator Mathias, the ranking minority member of this Subcommittee has stated so cogently (hearing record before the Subcommittee on Separation of Powers, Congressional Oversight of Administrative Agencies (The Cost of Living Council), October 9, 1973, vol. 1 p. 3):

"[T]he ability of individuals and corporations to both know the nature and extent of their obligations under the law and to effectively state their case is of paramount importance to the Subcommittee. This much seems clear—no program will long retain, or deserve, popular support if its decisions are not arrived at by a process which appears open, fair, consistent, thorough, rational, and enforceable, and of course, necessary."

It is appropriate that we begin our oversight hearings with examination of the Food and Drug Administration. The FDA exercises broad power in several areas vital to the health and safety of all Americans. Regulation of food, drugs, and cosmetics—those things that we put in and on our bodies—and the exceedingly complex and powerful food, drug, and cosmetic industries which distribute these products, places tremendous responsibility in and imposes very difficult duties on FDA. As the FDA stated in the preamble to its new procedural regulations: "The matters handled by the Food and Drug Administration, governing the safety, effectiveness, functionality, and labeling of consumer products that represent over 25 percent of the consumer dollar spent daily in this country, vitally and directly affect the interests of every citizen." Thus, it is imperative that we insure that the FDA is operating within its congressional mandate.

The first Federal food and drug law, the Food and Drug Act of 1906, was signed into law by President Theodore Roosevelt. Substantial amendment of this organic legislation occurred in 1938 with passage of the Federal Food, Drug and Cosmetic Act. This Act substantially revised the authority of the Federal Government to protect the public against adulterated and misbranded food and drug products. Cosmetics, which had not been regulated prior to this time, were placed under Federal supervision.

The basic purpose of the Food, Drug and Cosmetic Act is protection of the public health and safety. More specific statements of this purpose appear in the cases which hold that the Act's purpose is to secure the purity of drugs, and to protect the consumer from the hazards of adulteration, mislabeling, and misbranding, and from products that are dangerous, deleterious, illicit and noxious, or have not been proven to be safe and effective for their alleged uses.

As I briefly remarked earlier, we are concerned today with the role of administrative and regulatory agencies in our tripartite scheme of government, not the substance of FDA policy decisions. This hearing is quite timely, for regulations governing FDA's administrative practices and procedures were published in the *Federal Register* on May 27th. We hope to closely examine these regulations as well as those practices and procedures which were employed previously by the agency. We are also concerned about FDA implementation of its public information obligations under the Freedom of Information Act and its 1974 amendments. Thus, examination of the public information regulations issued on December 24, 1974 would also be appropriate. The purpose and function of FDA Advisory Committees are other areas which should be discussed because of the special separation of powers issues raised by their operation. While the topics and areas I have just mentioned are important and provocative ones, they serve only as starting points and are meant in no way to limit the scope of discussion.

I encourage and anticipate a free and frank discussion of the role of the FDA. With the cooperation and assistance of all of our witnesses, I trust that our examination of these three exceptionally important and powerful Federal agencies will make a meaningful contribution to the ongoing effort to insure that the operations of each agency fulfill the purposes which the Congress intended in establishing them.

I welcome our first witnesses today from the Food and Drug Administration—Dr. Alexander Schmidt, the Administrator of the agency and Mr. Richard Merrill, the new General Counsel. At the outset, I want to commend them and the other agency employees, especially Mr. Merrill's predecessor, Peter Hutt, for their hard work on the new regulations pertaining to public information and agency procedures.

Senator Abourezk. I welcome our first witness today from the Food and Drug Administration, Dr. Alexander Schmidt, the Commissioner of the agency; and Mr. Richard A. Merrill, the new General Counsel. At the outset, I want to commend them and the other agency employees, especially Mr. Merrill's predecessor, Peter Hutt, for their hard work on the new regulations pertaining to public information and agency procedures.

Dr. Schmidt, if you are ready, I guess we are.

TESTIMONY OF ALEXANDER M. SCHMIDT, M.D., COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY RICHARD A. MERRILL, ASSISTANT GENERAL COUNSEL, FOOD AND DRUG DIVISION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; SAM D. FINE, ASSOCIATE COMMISSIONER FOR COMPLIANCE, FDA; AND ROBERT C. WETHERELL, JR., DIRECTOR, OFFICE OF LEGISLATIVE SERVICES, FDA

Dr. Schmidt. Thank you very much, Mr. Chairman.

I am accompanied also this morning by Sam Fine, on the left, who is our Associate Commissioner; and also, Mr. Robert Wetherell, Director of our Office of Legislative Services.

With your permission, I will go through my statement, abridging parts of it so as to cut down the time it will take.

We are pleaesd to be here to discuss the regulatory and administrative procedures of the Food and Drug Administration.

We have very broad jurisdiction, as you have noted. We are responsible for four basic classes of products: Foods, drugs (both human and animal), cosmetics, and medical devices. In addition, under other laws, we regulate biological products, including vaccines and blood derivatives, and most items that emit radiation such as lasers, X-ray machines, and even color television sets. Products within our jurisdiction comprise a vast market and represent the production of nearly 100,000 different manufacturers.

Our basic regulatory objectives are simply stated: to assure that marketed products for which we are responsible are safe for use and perform as they are represented by labeling and, in some cases, by advertising. To achieve these objectives, we engage in four types of activities:

(1) We set standards for product composition and manufacture, performance, and labeling.

(2) We evaluate, prior to marketing, the safety and effectiveness of those products that must have premarket clearance.

(3) We conduct inspections, surveys, and analyses to monitor compliance with the statutory requirements with our administratively set standards, conditions of approval, and so on.

(4) And we initiate enforcement action where necessary to effect compliance with the laws and regulations we administer.

Historically, monitoring of already marketed products and enforcement through court action have been the mainstays of our regulatory approach. The basic statute, the 1938 Federal Food, Drug, and Cosmetic Act, prohibits the marketing in interstate commerce of foods, drugs, cosmetics, or devices that are "adulterated" or "misbranded," which is a classical term for things that are "unsafe" or "mislabeled."

Under this statutory scheme, the FDA's basic function was to discover and initiate court action against "adulterated" or "misbranded" products, and for many years this was our principal activity.

We did establish inspections, market surveys, and laboratory examinations to discover illegal products. And upon finding a violation, we would initiate court proceedings, usually consisting of seizure of the illegal product, which might also include injunction or criminal prosecution.

In short, the FDA functioned very much like the policeman on the beat, responding—and I think responding effectively—to violations that we encountered. But we increasingly found ourselves tied up in lengthy court battles, often litigating the same issue over and over again with different manufacturers. We also found that we sometimes were not able to discover a hazard or defect in a marketed product, and thus prevent harm before it occurred.

Since 1938, several developments have forced FDA to broaden and redirect its regulatory focus. Both Congress and the agency came to recognize the limitations of after-the-fact, case-by-case enforcement. Moreover, during the past generation, the industries subject to FDA's jurisdiction grew dramatically in number and size, and their products

became more numerous and complex. Regulation of this burgeoning market principally by court action proved inadequate both because of the immensity of the task and because the issues increasingly called for the melding of the best possible science with sound legal practice.

In the years following 1938, Congress enacted several amendments to the basic act which authorized the FDA to require scientific documents before products could be marketed. The 1938 law granted the agency authority to assure the safety of new drugs, prior to marketing. Congress gave FDA similar authority over pesticide chemicals in 1954, over food additives in 1958, and over color additives in 1960. And, in 1962, Congress gave us explicit authority to demand premarketing proof of effectiveness—in the form of well-controlled medical studies—for new drugs. These legislative changes enabled the FDA for the first time to prevent the marketing of untested and unproved products, rather than having to react to violations after they occurred.

These amendments also had the effect of shifting to manufacturers the burden of supplying proof that the law's requirements that products be safe and perform as represented were, in fact, met.

During the past decade, it also became apparent that the statutory remedies of seizure, injunction and prosecution are not by themselves adequate to assure prompt and efficient removal of harmful products from the market. The agency has responded by making increased use of product recalls, which place primary responsibility for removing hazardous products upon the companies involved in their manufacture or distribution, while FDA monitors performance.

FDA also became concerned that the failure of many manufacturers to comply with regulatory requirements was sometimes a result of our own failure to specify what the requirements were. We, therefore, began to promulgate regulations and provide guidance with the purpose of spelling out the responsibilities of industry. Among the products of this effort are our good manufacturing practice regulations, product standards, various voluntary compliance programs, and broadened educational activities. A central objective of our efforts has been to help industry fulfill its responsibility to manufacture and market safe products in the first place, thus freeing FDA to concentrate its resources on monitoring compliance with concrete standards established through sound administrative procedures.

Our present regulatory approach thus involves increased reliance on administrative standard-setting for product performance and manufacture. The process of standard-setting, and in fact all agency activities, has become increasingly important to the public and to the regulated industry. We have come to recognize the benefits of opening up our decisionmaking to public scrutiny and of broadened involvement by interested persons and experts outside the agency.

We think that our best illustrative example of the approach that we are increasingly using is our OTC drug review, the review of over-the-counter or nonprescription drugs. This program illustrates well the administrative procedures that we are now employing, and shows how the public can effectively participate in our decisionmaking.

The OTC drug review was instituted to respond to the need to assure that nonprescription, or OTC, drugs are safe and effective.

Because of a statutory exemption, many nonprescription drugs had been marketed without agency approval of their safety or effectiveness. Using our time-honored, conventional procedures, the only way we could have taken action against the somewhere between 4,000 and 5,000 new products that are on the market was through individual lawsuits based on charges of adulteration or misbranding. Such an undertaking would have been impossible because of the number of products involved—an estimated half million. Moreover, in the few cases the agency did attempt—our legal challenge was frequently mooted by the company's decision to reformulate or relabel its product—forcing us to start over again, often instituting another suit.

So, confronted with the prospect of prolonged and indecisive litigation, the FDA decided to develop a systemic, industrywide approach to regulating the entire class of OTC drugs. Our current approach involves the development of drug monographs, in the form of regulations, which define safe and effective formulations, and proper labeling for entire categories of related products.

The monographs are at the heart of the OTC drug review and the procedure by which these monographs are being developed embodies several novel features. Each monograph is initially developed by an advisory panel, comprised of medical experts from outside the Agency. These experts share their knowledge and experience from outside the agency and provide independent judgments in making recommendations respecting proper product formulation and labeling. Most meetings of the advisory panels are open to the public. Each panel listens to presentations and reviews documents submitted by scientists, consumers, and industry. Meetings are closed only when discussion will involve trade secrets or other confidential information, or during final committee deliberations.

Each OTC review panel includes, as members, a representative of consumer interests and a representative of industry nominated by the interested groups. These liaison representatives attend even the closed meetings of the panel. Their role, unlike that of the other panel members, is to represent a particular constituency and to transmit information between the panel and the groups they represent. The consumer and industry representatives participate in all panel deliberations but do not have a vote.

The OTC review is structured to provide maximum opportunity for public input into the agency's decisionmaking process. There are numerous stages at which interested parties can make known their views on the issues to be resolved. Any person may make an oral presentation to the expert review panel, or submit written documents that will be made a part of the record. After a panel makes its report evaluating individual ingredients and label claims for the entire class of products for which it is responsible—for example, laxatives—the report is published in the Federal Register and given wide circulation. Any interested person has an opportunity to comment on the report. After considering these comments, the Commissioner publishes a tentative order, proposing a regulation, which is once more subject to public comment. In addition an opportunity is provided for oral argument in a public hearing that is chaired by myself. At the conclusion of these procedures, the agency publishes an order promulgating a final monograph, which is subject to immediate court review.

The procedure I have described is very open to the public. Thus, interested persons and the general public are aware at all times of the direction in which the agency is heading. If consumers, scientists, or manufacturers disagree with a position that is being advanced, they are able to raise objections in a proper forum and at a time when their views have some prospect of influencing the ultimate decision.

The system also affords manufacturers advance notice of the changes that will be required of them. As a result, many companies have reformulated their products or revised their labeling to meet the requirements of a monograph even before it has taken effect. The high incidence of voluntary compliance with the OTC drug monographs that is occurring will greatly simplify the agency's task of enforcing the regulations once they become final. However, because all manufacturers may not voluntarily comply with monographs, we will monitor performance by conducting inspections and sampling products. Where violations are found, we will undertake to enforce the monographs by means of judicial remedies: through seizure, injunction, or criminal prosecution.

In implementing this comprehensive regulatory program, the FDA has faced a difficult problem of how to deal with products currently being marketed during the transition from the old "drug-by-drug" approach to the regulation by product class. Problems of transitional enforcement arise whenever a change is made in regulatory requirements, whether by statute or by administrative rule. We could have, of course, continued to pursue individual products through court actions, relying on the "adulteration" and "misbranding" provisions or attempting to expand the new drug requirements. As noted before, however, such an approach would have produced difficult, and in many cases pointless, litigation. Instead, the agency decided that, during the period monographs were being developed, it would not challenge the marketing of individual products except when they posed a safety problem or represented an obvious fraud.

A final element of our regulatory approach to OTC drugs that should be of interest to your subcommittee is our effort to insure that differing requirements are not imposed on the same products by different regulatory agencies. The FDA can control the formulation and labeling of nonprescription drugs, but it has no jurisdiction over their advertising, which is the responsibility of the Federal Trade Commission. To assure that the requirements of our two agencies are consistent, we have worked closely with the FTC since the inception of the monograph program. And the Federal Trade Commission now plans to adopt FDA's labeling requirements as standards for evaluating OTC drug advertising.

The OTC drug review encompasses what we believe to be the best of our administrative procedures: A well-understood process of setting forth formal requirements to be met by an entire class of manufacturers, worked out in public, with ample opportunity for public participation. The process is open, candid, and effective. It allows the agency the benefit of the best scientific expertise in the world, but results in practical regulations that can be efficiently enforced.

We hope to extend what we have learned in the OTC review to other product classes, and improve the process as we do so.

Certain other important features of our administrative regulations that I mentioned, Mr. Chairman, merit brief discussion now.

These regulations set out in great detail the rules governing all of our administrative practices and procedures. The regulations explain in clear, detailed fashion how new segments of the public can participate effectively in our activities.

For example, the new regulations describe clearly how citizens can petition the agency. We have provided a standard form petition to make it easier for individuals to take advantage of this right. Under our regulations, we must respond to any request for action within a reasonable period, and explain why we have or have not taken the action requested.

The regulations contain detailed procedures governing formal and informal rulemaking and adjudication. A feature particularly worth noting is the provision for establishment of public boards of inquiry. A person who, under the law, has a right to a formal trial-type hearing may elect instead to request a hearing before a public board of inquiry. Members of a board of inquiry will include nominees of the parties requesting its establishment. An adjudicatory hearing may drag on for months before issues are resolved, and trial-type procedures are not well suited for resolving complex scientific questions. A board of inquiry represents a novel way of permitting issues to be promptly resolved on their scientific merits rather than in an adversarial context. Our first board of inquiry will be convened soon to consider the safety of the artificial sweetener, Aspartame.

We have established procedures for recording agency interaction with outside parties. Thus, when an FDA employee talks with a private party about a pending regulatory matter, except when the purpose is solely to provide information, a written memo recording the substance of the conversation must be prepared by the employee. This requirement applies whether the conversation was by telephone or in a meeting. The memorandum becomes part of the public file of the case.

The regulations also require us to maintain two types of public calendars. The first is a weekly prospective calendar, which lists all public meetings, seminars, conferences, advisory committee meetings, public hearings, and other public proceedings of the agency. In addition, we publish a retrospective calendar of private meetings held the previous week by all top agency officials with persons outside the Federal Government.

Mr. Chairman, you mentioned our freedom of information regulations, which have been instrumental in opening FDA's records and files to public scrutiny. These regulations represent an effort to resolve publicly, and in advance, questions of disclosure that arise frequently under the statutes we administer, rather than making such decisions case-by-case, which would result in delay and inconsistency.

The Freedom of Information Act and our implementing regulations have produced some unexpected consequences. We currently are receiving upwards of 250 freedom of information requests per week, many of them demanding enormous documents and raising complex issues. We estimate that the uncompensated cost of responding to these requests will exceed $700,000 this year. Furthermore, about 88 percent

of the FOI requests that we receive are from private attorneys and industry. Only 12 percent come from the general press, consumers, health professionals, and scientists. One can question whether the expenditure of public funds is going for the purpose envisioned by the Congress in passing these amendments.

This latter trend, I confess, has been disappointing to me, but I am convinced that the policies we are striving to follow—stressing openness and public participation—strengthen the agency, and increase public confidence in the integrity of our decisions.

It is essential that a Government regulatory agency operate in this fashion. The FDA is committed to procedures that permit us to deal openly and fairly with all persons affected by our decisions. We believe our new administrative procedures will improve communication and assure sound and expeditious disposition of the difficult and sensitive issues which the agency continually confronts.

We are currently at work codifying the agency's enforcement practices and procedures. This codification will include regulations relating to imports, criminal prosecution, recall and detention of products, publicity, and issuance of regulatory letters. These regulations will complete our efforts to paint a full, public picture of FDA's regulatory activities.

Mr. Chairman, we appreciate very much the opportunity to present this statement. We would be anxious to try to respond to any questions that you may have.

Senator ABOUREZK. Thank you, Dr. Schmidt.

What is the present status of the agency's legal authority to both institute and conduct litigation in the Federal courts?

Perhaps you would like to have counsel answer that.

Dr. SCHMIDT. Are you referring to how we work with Justice?

Mr. MERRILL. I think your question is directed to whether we can go to court or not. When we want to go to court to seize a product, to exercise a criminal prosecution, or sue for an injunction action, we file a recommendation through the Justice Department, either the Federal office or the U.S. district attorney, or through the Justice Department here, for practical purposes, if we are seizing a product.

Criminal prosecutions are reviewed here in Washington as well as in the field. It is quite clear that the Justice Department exercise a more attentive judgment to those matters, and also on questions of injunction which raise serious questions.

Senator ABOUREZK. So all matters, civil or criminal are handled by the Department of Justice. Does the Department respond like you want it to?

Mr. MERRILL. Frequently yes, and sometimes no.

Senator ABOUREZK. What is the percentage?

Mr. MERRILL. Can I provide that for the record? I will try to give you some detailed information.

Senator ABOUREZK. Yes.

[The information referred to follows:]

Testimony before Congress in 1972 indicated that approximately 30 to 35 percent of all criminal referrals were terminated over the Food and Drug Administration's objection. More recently, our review of criminal referrals for calendar years 1972–1974 indicates that approximately 25 percent of these cases

still are being terminated over FDA objection. These terminations take the form of refusal to file the case, refusal to include all defendants or counts, and dismissal of defendants or counts. In some instances, the Agency has not been given full opportunity to present its views before a proceeding was terminated.

Mr. MERRILL. In seizure actions I think it is fair to say that we have little difficulty in dealing with either the U.S. attorneys or the Department of Justice. In criminal prosecutions, they frequently will refuse to file a recommendation for prosecution.

In two recent instances criminal prosecutions brought against both corporations and individual defendants have been settled by the U.S. attorney without consultation with us. In both of these instances we have written letters, not as mild as perhaps they should have been, pointing out that we thought we ought to have been consulted because we had primary responsibility for protecting the consumer.

We got two quite different responses; in one instance, an expression of a desire to cooperate more fully; in the other we were in effect told to mind our own business.

Senator ABOUREZK. That is what you were doing.

Dr. SCHMIDT. Another small point is that our lawyers spend a lot of time worrying about and working with Justice when cases are tried before a court. I think some of our feeling is the "Please, mother, I would rather do it myself" type of feeling, which may or may not be all that valid. But sometimes I have observed that people who have worked with and lived with very complex cases for years are better able to understand the issues involved, and so are better able to handle cases than lawyers assigned from Justice, who may come in a little late in the day.

Mr. MERRILL. I think that is the critical point. I don't have any fault with their competence. They are very good, and I am not in a position to say that we could do a better job technically in many cases. I think we could do at least as good a job. But it is very hard for a Department of Justice attorney who has not lived with a problem for 2½ years to explain what it is that the agency is trying to do and how this fits together with three or four other things that the agency is doing that are not directly involved with the case. It seems to me that we often don't litigate with our best foot forward.

Senator ABOUREZK. I think that the fact that you have a separate agency that sometimes goes on its own on legal determinations obviously inhibits your enforcement ability.

Mr. MERRILL. I think it injects a factor into our judgment and preparations that we think ought not to be there.

Senator ABOUREZK. But is it inhibiting your enforcement capability?

Mr. MERRILL. It is.

Senator ABOUREZK. Do you have any suggestion as to how this might be remedied?

Would you suggest that having your own legal staff might be a remedy for it?

Mr. MERRILL. That seems to me the ultimate solution, Mr. Chairman. I think that we ought, eventually, to be able to represent ourselves in court, to initiate our own proceedings. I think that there would be transition problems if that authority were given to us tomorrow, because we would then have to staff up in the districts where we have no attorneys now. All of my attorneys are in Washington, with one ex-

ception, one is in Los Angeles. In order to institute and monitor all of the seizures—the product actions that we have that are spread across the country—we would have to double our staff overnight, and eventually go higher than that. But that seems to me the eventual solution.

Senator Abourezk. Can you tell me of any other areas where congressional action which would expand FDA's authority would increase your efficiency?

Dr. Schmidt. During the past several years, the administration has submitted to Congress some suggested amendments to the Food, Drug, and Cosmetic Act. Both Houses have put forward bills which to date have not passed, but which would give us additional and needed authorities.

Principally these include the following points: (a) Requirements for registration of manufacturers and their products. (Oftentimes we really don't know who is out there maintaining something and that makes it awful difficult for us to seize the product.) (b) Certain types of recordkeeping we feel are necessary. (c) Subpena authority for records in particular, an authority that most regulatory agencies have and that we have never had. (d) Authority to detain products so that they are secure while we are getting injunctional seizure action would prevent products being moved before we can get court action. It is discouraging to find out that the product you are after has disappeared over a weekend—which has occasionally happened—and has been introduced in interstate commerce. Thus, we feel our ability to detain products for a limited period of time while seeking court action would be important.

There are two or three other areas that are not entirely discrete, and are admittedly more difficult to come to grips with. But we feel the need of congressional review and deliberation.

The first of these is whether or not there can be an easier way for us to take products off the market that now exist. As things now stand, something either has to be declared an imminent health hazard, in which case we can move quickly, or else we go to court and go through our existing administrative procedures, particularly the adjudicatory procedures, which can drag on sometimes for months and even years before we can get something off the market.

There are cases where I may not be willing to say definitely that something is a hazardous product, but where I have a strong suspicion that it is. And the question arises as to whether the public should be protected from this product during extended court procedures or not. So this area, and our hearing procedures which are very cumbersome, need reviewing.

The final thing that I would mention is the whole area of trade secrets. I believe that Congress should look at the trade secret provisions of the law and the language that has to do with commercial information and so on to see if indeed we are not keeping confidential more things than we should or need to. And in particular, I am concerned about some of the evidence from scientific studies that are now confidential.

So that is a list of a number of things that we have been concerned about over the last few years.

Senator Abourezk. The field structure of the FDA consists of 10 regional offices. Would you explain what your national office has done

to assure uniform implementation by the regional offices of the statutes and regulatory programs for which you have responsibility?

Dr. SCHMIDT. We have the regional offices. In addition, there are a number of district offices and field stations, so that we really have a greater distribution of the agency than just in 10 locations. And about half the agency is in these field offices. So it is a substantial force.

I would mention two or three things, in response to your question. The first is that the administration of the field offices comes under an individual in my office who has essentially daily communication with the field offices through direct teletype and telephone linkages.

There is a regional director who is responsible for the operation of his staff. And he is involved frequently at headquarters in the definition of policy and exploration of programs. And he is responsible for the consistency of the field activities. There is a lot of communication with the field offices and the different headquarters offices. So that field staff working, say, with a problem, communicate with the Bureau of Drugs, and they communicate with the General Counsel's office. Thus, we have a kind of matrix set up with cross-communications. With some minor exceptions, I have not seen in the past 2 years any area going off on its own as a result.

I think that our enforcement activities are really quite remarkably consistent. Every once in a while one area, because of its location, say, in California, will take up a particular area and develop a special expertise. But in general I think we are remarkably uniform.

Mr. FINE. I might add a little to that.

We have a rather elaborate compliance program system that we have evolved over the years. Each bureau—and there are six bureaus in the Food and Drug Administration—develops compliance programs. Input is given to the compliance programs by the headquarters unit, which is called the executive director for regional operations. Ultimately the compliance programs come to me as the Commissioner's representative to approve before they are issued to the field.

In carrying out the actual legal enforcement actions under the compliance programs, whether it be prosecution or injunction as opposed to seizures, we have a very elaborate review process to insure uniformity so that we don't have, let's say, undue severity in the regional headquarters in San Francisco, as compared to a similar case in the regional headquarters at Atlanta. We require that the compliance officer at each of the districts submit their recommendations to the regional director; he personally signs off on these to insure that all actions are in compliance with our policy. They then come in to the appropriate bureau, whether it be food, drugs, devices, and so on. And again there is a very careful review.

The next step is referrally to the regulatory management staff in my office, which does a careful review. From there, the cases go to Mr. Merrill's office, the General Counsel's office.

And of course you have already asked the question. We again have a review by the Department of Justice.

I spent my first 29 years in Food and Drug in that field force. And I dealt many times with assistant U.S. attorneys and U.S. attorneys. I can tell you that they do look very carefully at our cases, and they do apply further judgment.

So I want to assure you that there is much review of our cases in order to assure uniformity.

Senator ABOUREZK. You are a part of the Department of Health, Education, and Welfare. Would you please explain how the functions of the Department are delegated to the Food and Drug Administration?

Dr. SCHMIDT. Basically, the chain of command is from the Secretary of HEW to the Assistant Secretary for Health, and then to me. The Secretary delegates to the Assistant Secretary, who in turn delegates to me. And in practical terms what happens is that we are left pretty much alone. I have noted in most of the things with which we deal the Secretary doesn't have anything to do with it. The problems are such that they are not subject to someone spending 10 or 15 minutes or an hour or getting briefed on them and then making a decision. One is sort of immersed in these problems day in and day out, and weeks on end, and the decisions are evolved. So, first of all there is a delegation of responsibility and authority, and then second, there is an agreed-upon degree of autonomy for the agency that I think is absolutely necessary. In my 2 years with Secretary Weinberger, it has worked very well.

Senator ABOUREZK. Do you believe that you have the same kind of powers delegated to you as an independent regulatory agency?

Dr. SCHMIDT. No; in a number of areas I do not. The question then becomes, is this an impediment or has it been an impediment with minor exceptions, the answer is no. I learned through the years that everybody has a boss, and the idea that somebody can be fully independent is really kind of ludicrous.

Second, the principal issues, if one wishes independence, are budget and personnel systems. And by and large, we have not suffered from working with the Department in the preparation of budgets and in personnel matters.

Senator ABOUREZK. In an article which appears in the July 7 issue of the Food, Drug, and Cosmetic Reports, drawn from an interview with HEW's information officer, the author notes that FDA is engaged in a new battle to save its freedom of information regulations from an onslaught from highly placed people in the Department who challenge FDA's authority to issue its own regulations. The author claims that HEW officials are moving to nullify your regulations, and that the intragovernment dispute is now being marked by strong language and strong feelings.

Now, does this article accurately represent the present state of affairs?

Dr. SCHMIDT. No, I don't think so. I told the individual concerned that if he moved to nullify our regulations it would be the last move he ever made. But I don't think we have used strong language.

Senator ABOUREZK. I hope you continue that kind of harmony.

Dr. SCHMIDT. I have spoken with the Assistant Secretary involved in that area, and he said that that was inaccurate. Their concern was that our regulations be consistent with the departmental regulations, and I must say that I agree with that need. The issue that arose was whether or not in some administrative areas the delegated authority to me to issue regulations independently was extended to the agency.

What we have done is work out an MO such that we promulgate regulations "independently." Mr. Merrill, who is a member of the General Counsel's office, signs off on these regulations as the Secretary's representative. So, we have said that they really are not all that independent anyway, since he serves as the Secretary's representative.

But I do believe there is a need to pin down the Commissioner's authority to issue the regulations, and I will be discussing this with the new Secretary.

Senator ABOUREZK. Will the upshot of this debate be a diminishing of the information flowing from FDA?

Dr. SCHMIDT. You say in reconciling any differences between our regulations and the Department's, what will the net effect be?

They have been picayune sort of things. We thought that part of theirs were dull and they thought part of ours were dull, and we are resolving these.

Mr. MERRILL. I don't think that we really know the answer to that. I think that they believe we have made the system too complicated. And it is a complicated system. We have records that, notwithstanding what has been said, are somewhat distinctive in the Department. They contain, for example, information about a lot of individual patients, enormous numbers of individual patients. And we have to excise those names to protect their privacy.

In addition, the trade secrecy issue is really the point on which I think we are most concerned.

We believe that under our statute we must protect a lot of information that is available in our files, not only under the freedom of information law, but under the Food and Drug Act, which prohibits its disclosure. And I think the Department may have the view that perhaps more time can be made available.

I think that they have not had an opportunity to look at the information to base that view on.

Senator ABOUREZK. Dr. Schmidt, do you believe that Congress ought to reexamine what can be released?

Do you think that more of the trade secrets can be released without damage?

Dr. SCHMIDT. Yes, sir.

Senator ABOUREZK. Is this seeming rift between HEW and the FDA part of an ongoing conflict over other matters besides freedom of information?

Dr. SCHMIDT. Yes, and no—probably no. But I must say that in my 2 years in this job there has only been one subject area of disagreement that has arisen, and that is in our issuing certain kinds of regulations. We have had disagreements with individuals in the Department about our freedom of information regulations, NEPA regulations, Environmental Protection Act regulations, and things that come under those, such as the plastic bottle environmental impact statement. I have had no disagreements with the Secretary, the Assistant Secretary of Health, or the other Assistant Secretaries. But there are people in the hierarchy who get quivery lower lips when they feel that they have not had their offices satisfied. And this really comes to the basic issue of whether we can promulgate regulations independently or not.

I feel that we should be able to; that it is my responsibility to assure that they are consistent with departmental regulations, which

in this case would be over ours. And I believe it is my responsibility to be sure that the departmental offices have ample opportunity to comment on our regulations. But I feel that it should be my prerogative to decide after hearing the comment of a staff person at the Department level whether or not our regulations need to be consistent in this particular way as opposed to another particular way. I am not interested in arguing minor editorial matters with staff and the Department. But this area is the only area in which we have had some disagreements with the Department, other than just the usual kinds of things that we would be arguing with OMB or the White House or anybody about.

I do feel obligated to say that there are some very sound advantages for the FDA being in HEW. Principally, the advantage is that I sit with the head of NIH and the heads of the other health agencies. And we are a part of the Public Health Service. The ease of communication, my ability to call on the Cancer Institute for help, and so on, is facilitated by our being in HEW.

Senator Abourezk. You do not think FDA's becoming independent of HEW would be the better thing to do?

Dr. Schmidt. No. If I could have my druthers right now I would nail down the important areas in which we have to have independence, but then leave us in the Department as part of the Public Health Service.

Senator Abourezk. Obviously the little argument that you have had with the Department over the freedom of information has hurt your efficiency regulations—in fact, that is what it seems to be most often, arguments over how the regulations are promulgated and so on—if you could get the freedom to do your own regulation writing, would that pretty well solve your problems with the Department?

Dr. Schmidt. I think so. I think the idea of submitting an independent budget, for example, is a great thing, but that idea is sort of a delusion. One can sit and think of areas in which he would like to be able to just snap his fingers and do things, such as appoint members to advisory commissions and so on. But I think that clearly the most important area is that of regulation promulgation.

Senator Abourezk. You said in one of your responses that the lines of delegation of authority from HEW to FDA are unclear. Would you just give me a little more detail on that?

Mr. Merrill. I think they are not unclear now. I think there may be questions about whether they should be altered. We do not have any question. We believe that the Commissioner has been explicitly delegated authority from the Secretary, through the Assistant Secretary for Health, to adopt all regulations for the efficient enforcement of the Food and Drug Act, that is, all substantive regulations. We believe that delegation also extends to administrative regulations, under such statutes as the Freedom of Information Act, the Privacy Act, and NEPA. The General Counsel of the Department, Mr. Rhinelander, has written a memorandum in the context of NEPA saying that he agrees with us. Our concern would be that this arrangement should not be altered, and desirably ought to be crystalized in something harder than an annually renewed delegation of authority.

Senator Abourezk. You said in your opening statement that FDA

is presently at work codifying the agency's enforcement practices and procedures. When do you think this work will be completed?

Mr. MERRILL. Mr. Chairman, that work is currently going on. This is another instance where we have tried to coordinate the activities of the central agency with those in the field. That work is going on through a tripartite arrangement between my office, Mr. Fine's office, and the field offices. We are going to set up individual task forces of three or four people to draft regulations in each of these areas. I would guess that we would have drafts for circulation within the agency sometime in the early fall. I do not know what the promulgation schedule is likely to be, but I would guess that we would have something in the Federal Register certainly before the end of June of the following year, 1976.

Senator ABOUREZK. Several sections (348(g), 355(i), and 360(h)) of the act provide for judicial review of certain actions of the Secretary by filing in the Court of Appeals for the District of Columbia or for the circuit wherein the petitioner resides or has his principal place of business, but review of orders of the Secretary issued pursuant to section 371 of the act must be sought in that circuit where the petitioner resides or has his principal place of business.

Does the fact that provision is made for appeal to different courts cause problems?

Mr. MERRILL. It has not caused problems in my experience, and I think Mr. Hutt would say the same thing, at least with respect to those provisions of the statute which authorizes review by the court of appeals. It is an anomaly for the same statute to confine appeals in one area and to give complete choice in others.

Senator ABOUREZK. But would it not be preferable to have all appeals filed in the District of Columbia?

Mr. MERRILL. I do not see particular advantages to us. I think our batting average in the District of Columbia Circuit Court has not been terribly good, but that is not a product of the statute.

Senator ABOUREZK. On May 27 of this year, the FDA published in the Federal Register comprehensive regulations on administrative practices and procedures. While I can appreciate the magnitude of this undertaking, I have some questions pertaining to these regulations.

First of all, while only one of the five types of public hearings provided for in the regulations is conducted before the Commissioner, the final decision as to agency action as an outgrowth of each of these proceedings is vested in the Commissioner. In addition, it seems that virtually all other agency decisionmaking of a regulatory nature is made by the Commissioner.

Now, does this concentration of decisionmaking power at the top of the agency place tremendous time burdens upon you and prevent you from carrying out effectively some of your policymaking functions?

Dr. SCHMIDT. Well, I have thought a lot about the way the agency is structured, and I have talked with Commissioners of other forms of Commissions, and so on. It is very clear that the way the Food and Drug Administration is set up is efficient for the rapid types of decisionmaking that we have to do at times. I think that it is necessary for the Commissioner to spend the time required to notice the issues, to follow the various developments, so that in conjunction with the staffs of the bureaus, bureau directors, and the Commissioner staff, the right decision can be arrived at. Generally, I have set up a system, for exam-

ple, when advisory committees meet, there is a memorandum prepared that comes to me on the activities of that advisory committee at that meeting, so that I can follow along all of the advisory committees and what they are doing.

Similarly, through bureau staff meetings and other procedures, I can come up with the issues, and do not find it a burden to have that kind of involvement in agency activities. As a matter of fact, it is an absolute must. And the idea that six people can be better does not really appeal to me, because every one of those six has to do the same sort of keeping up if they are to be responsible for one-sixth of the decisionmaking.

The reason I hesitate before I started to answer the question is that one does need to devote a certain amount of time to that kind of involvement in the issues. Yet I have had periods when I have spent 60 percent or more of my time in testifying before Congress and becoming involved in other activities that might be terribly important, but are not directed at my understanding the issues and being engaged in decisionmaking.

So one makes up for that by working nights and weekends, and so on.

Senator Abourezk. Thank you.

Mr. Tobias. The preamble to the new regulations state that they are to be effective on the date that public comment is due, and that "any changes warranted by such comment will be reflected in a further order modifying these new regulations."

This manner of proceeding seems to foster a built-in bias and inertia on the part of the FDA in favor of retention of the regulations in the form they were issued. I say this because personnel in your Public Records and Documents Center informed me last week that no further modification has yet concurred in the public information regulations, which were issued in December in the same manner.

Mr. Merrill. Mr. Tobias, I think I can respond to that, first with respect to the freedom-of-information regulations.

The regulations issued in December were a final order that followed a proposal of some 18 months or more prior to that, on which we afforded a full opportunity for public comment. And they were finished in December, with an invitation to comment once more.

A lawyer in my office has spent most of his time since joining us, developing modifications of the regulations, and we will publish a final set of freedom-of-information regulations some time in the next 2 or 3 months, reflecting some changes. The answer you got is quite correct; there have been none yet, but that does not mean that they are not in the works.

With respect to the decision to make the procedural regulations effective following the conclusion of the comment period—which, incidentally, has been extended for 30 days—we faced a dilemma.

We wanted people to feel free to show us where they thought these regulations ought to be changed, and people are feeling free to do that. We are receiving a lot of comments.

But the regulations also cover activities of the agency that go on. We cannot simply stop listening to citizens or engaging in rule meetings. And we also wanted to begin to acclimate people in the agency as best we could to the procedures that were outlined here.

There is no doubt that these procedures represent a preliminary commitment on the part of the agency management to proceed in this fashion. I think that is necessarily true when any agency issues a proposed

rule. We are going to make some changes, and we are already contemplating some. I have two back on my desk for introduction when we publish the final version of these.

Dr. SCHMIDT. As far as I was concerned, it was very important to promulgate these regulations and have them effective when they were, because in those regulations are procedures that are terribly important for the agency to follow. And I was not willing to spend more time without the agency following some of the procedures in there, such as recording their meetings with outside parties for the public calendar, and so on. My decision was to publish a long series of memos that would require what is in the regulations to be implemented because I wanted that done immediately.

Mr. TOBIAS. I can appreciate concern about having something in effect as soon as possible. I guess my difficulty comes with the fact that the new regulations, which are not nearly so complicated as the administrative practices and procedures regulations, will take approximately a year from the date of issue to be put in final form. And I take it that the same amount of time at least would pass before the administrative practice and procedure regulations are in final form. So it just seems that that leaves a fairly extended period in which there is a great deal of uncertainty.

Dr. SCHMIDT. I think that your use of the phrase "in final form" is a semantic item for thought. It is very clear to me that these regulations will be evolved over the next few years. And I expect substantive changes in the FOI regulations and the procedural regulations periodically, those periods not being too far apart. And we would expect to correct our code frequently. I do not think there will be a final form.

Mr. TOBIAS. In several instances, the language contained in the preamble which describes a particular section of the regulations far surpasses in scope the actual regulation itself. Do you recognize this as a problem?

Mr. MERRILL. I do not think so. I cannot claim authorship of either regulations, which is the work of the agency, the top management, and the preamble which is largely Peter Hutt's. The objective was that the preamble should attempt to explain in less technical language what it was that the agency was trying to do in the code. It is a method of communication. It is a setting of context. The risk that one runs is that you intimate or say things in the preamble that are not clearly spelled out in the regulations. We have encountered one such instance already, and we are going to make a change relatively promptly in that.

But I think that the loss of a preamble of this length with its great detail would be a net loss of information to people that are going to be subject to the procedures that the agency wants to observe.

Mr. TOBIAS. In those instances where the preamble seems to go beyond the scope of the regulations, do you intend to then supplement what is in the regulations?

Mr. MERRILL. There may be one or two instances where clarification of what is in the regulation is necessary. The preamble spells out procedures in somewhat more detail than the regulations themselves. And since eventually many people will have access only to the regulations, only the regulations will appear in CFR, for example—it will be essential that the regulations themselves be as fullsome and as de-

tailed as the preamble itself. So, we may have a little catching up to do. But I have not yet found serious inconsistency.

Mr. TOBIAS. There are a couple of instances where explanations are given in the preamble which go beyond the scope of what actually appears in the regulations themselves.

Mr. MERRILL. That is conceivable. And I hope you will bring them to our attention. Because we do not want doubt to remain about what the regulations require or permit.

Mr. TOBIAS. You mentioned the problem caused by the exemption for trade secrets contained in the Freedom of Information Act. What precisely would the agency suggest in terms of legislative change that might ameliorate some of the problems there?

Dr. SCHMIDT. There are two answers to that. One is that there are some things that I may feel personally; and the other is that there are things that others in the agency feel are now trade secrets and should not be. But in many areas, there is disagreement, particularly between those of us who are more liberal than segments in the industry. The concept of protecting economic advantage is really not one that revolves around safety of the product. The more we have discussed it the more I am convinced that it is a matter for Congress to take up and for Congress to decide whether or not, for example, data derived from human experimentation should ever be a trade secret.

I find personally troublesome the proposition that data derived from human experimentation when people volunteer for clinical trial can be kept as a commercial trade secret. That is just one example of something that a number of us feel quite strongly about. There are other areas in which we protect the kind of commercial information that does not let somebody run out and whip up a batch of whatever it is, but our keeping it confidential costs the taxpayers a tremendous amount of money. Whenever anybody questions something, we have to take all of the documents and have somebody read them. If it is a scientific thing, I have to have an M.D. or a Ph. D., sometimes, sit and read through all of this stuff to pull out the trade secrets. Now, it is a matter of whether it is worth the taxpayers funds to protect certain kinds of information that when you come down to a hard definition is really not a trade secret.

Mr. MERRILL. Let me provide just a little background on the secrecy of safety and efficacy data, because that is really the core of the problem. I do not think we are inclined to reveal the product formulation, nor would we disagree with industry that they ought not to be revealed. Those are classic trade secrets. But the data that a manufacturer generates to support approval of a new drug's safety and effectiveness—studies in humans and in animals—are secret because we read the law, and have since 1938, as requiring each manufacturer to obtain his personal license even for a very closely related or identical drug. That license is a private license.

Well, if the data that are generated by the first manufacturer can be used by the second without cost or investment, it becomes a public license.

I think Congress really ought to address the question of whether or not the new drug approval process should be a process for generating private licenses or generating some sort of class approvals

that would permit any manufacturer of a conforming product to put it on the market, patent protection aside. Until Congress does that, I think we are not in a position to make the safety and effectiveness data public, even though it certainly does lie at the heart of our decisional process.

Mr. TOBIAS. Sections 2.112 and 2.113 govern the filing of objections and requests for hearings on regulations or orders and rulings thereon. Section 2.112 requires detailed advance evidentiary presentation and section 2.113 requires that six listed prerequisites must be met before a hearing may be granted. However, numerous sections of the Food, Drug, and Cosmetic Act provide a right to a hearing to persons under certain circumstances. While the purpose of sections 2.112 and 2.113 seems to be reduction in the number of hearings held and the time consumed by them, such a result could be accomplished by other means such as prehearing conference rules which will limit the focus of the hearing to important issues and the summary judgment procedure provided in the new regulations. By imposing additional requirements through regulations upon a party entitled to a hearing by statute, the FDA seems to have qualified the statutory right to a hearing and exceeded its statutory authority.

Where does the FDA derive the authority to impose such requirements by regulation?

Mr. MERRILL. I think the answer to that lies in the Supreme Court cases that were decided in the spring of 1973, where the issue was the entitlement of a manufacturer to a hearing on withdrawal of a new drug that the agency had concluded was ineffective. The Court there said that was perfectly proper, under statutory provisions that seemed to grant an unqualified right to a hearing, for the agency to demand a very substantial threshold showing on the factual issue that the manufacturer wanted to dispute; namely, the lack of evidence of effectiveness.

There we had established very detailed regulations specifying what effectiveness meant, and what kind of studies had to be done, and what a manufacturer had to show, in order to show a disputable factual issue that would bring into play the hearing procedure that the statute specified. The Supreme Court, with a single qualifying vote, said that this was a perfectly appropriate procedure under the statute as it was written.

What we have tried to do here—and, incidentally, this is not much different functionally from what many other administrative agencies do—is to get potential parties to trial-type proceedings to lay all their cards on the table so that we know whether a trial is necessary, or so that we can expedite a trial. I am told, after interviewing some administrative law judges of various other regulatory agencies, that in several instances where a statute purports to require a hearing, no "hearing" ever takes place. It is all done on paper. The proponent is asked to submit his evidence, and the respondents are given an opportunity to document all of their evidence in writing, and the administrative law judge ultimately renders his decision without ever seeing a witness.

The procedure here is the prelude to a truncated hearing, a hearing in which live testimony will be had when it is appropriate. There is no

intention to avoid live testimony where it is necessary, there is an intention to see that we do report the three-ring circuses of the kind that we confronted when we tried to establish identity standards for vitamin pills.

Mr. Tobias. I can appreciate the problems, and I can see the direction in which you are heading. I guess the difficulty seems to lie in the fact that public hearings which are granted by right by statute seem to be taken away by the regulations. There are six or seven requirements that are listed in section 2.113.

Mr. Merrill. I do not think that is true. I think that the basic administrative law learning, which was simply confirmed by the Supreme Court, was that when Congress specifies that someone has the right to a hearing, this means a right to a hearing on disputed factual issues. It is perfectly appropriate, and indeed desirable, for a regulatory agency to try to narrow the area of dispute, and require from the person requesting a hearing, a sufficient showing, that we know that it is appropriate to go to trial.

Now, it may be that these regulations at first blush look as though they impose requirements that are more onerous than they need be. Again, I do not think our views are fixed in stone. If someone demonstrates to us that this particular requirement will really gut the statutory opportunity for a hearing, we are perfectly prepared to alter it or modify it.

Mr. Tobias. It seems from a reading of section 2.113 that the applicant must show that he will win in a hearing before he is granted a hearing.

Dr. Schmidt. I disagree with the implications of your statement. We consider these very carefully. It seems to me to be a clear statement of when the statutory required hearings come into play. It does not abridge the right whatsoever, but it clarifies issues such that injustice will not be done. I do not think Congress ever intended this procedure to be used to tie the agency up in yearlong processes. What we are trying to do is to state clearly when it does come into play and how it may be conducted in a way that is fair and reasonable for everyone concerned. I do not think defining terms abridges the right at all.

Mr. Merrill. Let me add one point.

The Food and Drug Administration has been accused of attempting to try to avoid all hearings. I think that is an unfair accusation. Mr. Fine and I would not have spent a good part of our last 2 weeks interviewing administrative law judges to come and work for the agency if we did not contemplate holding hearings. In addition, we have just scheduled a hearing where one is not required by statute, on proposed labeling for oral hypoglycemic drugs. The hearing will take place in August before the Director of the Bureau of Drugs. It is going to be a legislative type hearing, but still a live hearing. If anyone wants to come and tell us why we are wrong on the labeling, he is free to do so. This is a procedure in addition to any required by the Administrative Procedures Act or, indeed, by these regulations.

Mr. Tobias. I would like to ask you one more question about advisory committees.

In the preamble for section 2.370 of the new regulations it is stated that the "Commissioner has increasingly relied upon the use of standing technical public advisory committees for advice and recommendations on (medical and scientific issues) * * *," and, in the July 10 edition of the Washington Post, Dr. J. Richard Crout, Director of the FDA's Bureau of Drugs, stated that the drug phenformin has no role in the treatment of diabetes and is so dangerous that it should be taken off the market, but that this decision would have to be made by the FDA's Metabolic and Endocrine Advisory Committee.

In light of FDA's admission of increased use of such advisory committees and in light of Dr. Crout's statement and statements by others that decisionmaking is being made by FDA advisory committees rather than by the Commissioner, do you believe that the FDA is complying with the Federal Advisory Committee Act which requires that advisory committees be utilized solely for advisory functions and that determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government?

Dr. SCHMIDT. First of all, in the full context of Dr. Crout's statement we have been talking about the whole area of hypoglycemia and are going to advisory committees for advice and recommendations, and to obtain public and professional education about this subject. Dr. Crout said at the hearing that he did not believe there was a good reason for phenformin to be on the market. Senator Nelson asked why we did not take it off. And Dr. Crout said because we would have to go back to the advisory committee for their recommendations. In the context in which he was speaking, what Dr. Crout meant by this was that to do something like take phenformin off the market, in order for us to avoid court proceedings that have delayed our labeling in these matters for several years, we would have to have professional concurrence. And going back to the advisory committee for their recommendation was a necessary part of how we have gone about this process, that is, of getting professionals to make their recommendations to us.

I do not recall his stating precisely what is in that newspaper story. When I saw that newspaper story, I remarked in front of the witness, so I can verify this, that somebody is going to have to look at this and say that that is contrary to what we have said about our use of advisory committees. I have said repeatedly, and I will say it again, and Dr. Crout would say it, and has said it, that advisory committees give us advice, they give us recommendations, and they give us wordings. The answers to the questions that we pose to them, the decisions are the agency's decisions and not advisory committees. I would have to look at the transcript to see exactly what he said. I have not looked at it, but to the best of my memory, that story is incorrect in its quoting of Dr. Crout.

Mr. TOBIAS. How often do your final decisions as a Commissioner vary from the recommendations made by the various advisory committees that the agency has?

Dr. SCHMIDT. On occasion, but not very often. In the last hearing in which this question was asked of members of the advisory commit-

tee, they said "very seldom, and when that happened, it was with good reason," or words to that effect—I am paraphrasing the advisory committee. If indicated, I would not hesitate to overrule the advisory committee. But when we were contemplating that, it was because of recent information, or differing information, or different understanding that would come from deep involvement in the problem.

Mr. TOBIAS. Would you say, then, that you rely quite heavily on the recommendations of the advisory committeees in making your decisions?

Dr. SCHMIDT. Quite heavily. Because these recommendations represent in general the best advice of the best scientists in the country. And if I did not pay a lot of attention to it, I would not have the advisory committee in the first place.

Senator ABOUREZK. There are other witnesses this morning who have some criticism of FDA. I would hope that you or one of your representatives can stay around. And I would like to have some comment later from you about the criticism and what you might propose to do about this criticism.

So I want to thank you very much for an excellent statement, and for your appearance here today.

And we shall submit the additional questions to you. And we will hold the record open for 30 days for written responses.

Thank you very much.

Dr. SCHMIDT. Thank you, sir.

[The prepared statement of Dr. Schmidt follows:]

PREPARED STATEMENT OF ALEXANDER M. SCHMIDT, M.D.

Mr. Chairman: We are very pleased to be here today to discuss the regulatory and administrative procedures of the Food and Drug Administration (FDA). In the course of our testimony, I shall describe the basic regulatory objectives of the FDA and explain several recent innovations in the Agency's regulatory approach. We shall also respond to the several questions specifically raised in your letter inviting us to appear today.

SCOPE OF FDA RESPONSIBILITIES AND ACTIVITIES

The FDA has jurisdiction over products whose annual sales total approximately $110 billion and represent about 20 percent of the consumer's purchasing dollar. We are responsible, under the Federal Food, Drug, and Cosmetic Act, for four basic classes of products: foods, drugs, cosmetics, and medical devices. In addition, under other laws, we regulate biological products (including vaccines and blood derivatives) and items emitting radiation, such as lasers, x-ray machines, and color television sets. Thus, the products within our jurisdiction comprise a vast market and represent the production of nearly 100,000 different manufacturers.

The FDA's basic regulatory objectives are simply stated: to assure that marketed products for which we are responsible are safe for use and perform as they are represented by labeling and, in some cases, by advertising. To achieve these objectives, we engage in four general types of activities:

(1) Setting standards for product composition, manufacture, performance, and labeling;

(2) Evaluating, prior to marketing, the safety and effectiveness of those products that must have premarket clearance;

(3) Conducting inspections, surveys, and analyses to monitor compliance with statutory requirements, administratively set standards, conditions of approval, etc.; and

(4) Initiating enforcement action where necessary to effect compliance with the laws we administer and our regulations.

Historically, monitoring of marketed products and enforcement through court action have been mainstays of FDA's regulatory approach. Our basic statute, the 1938 Federal Food, Drug, and Cosmetic Act, prohibits the marketing in interstate commerce of foods, drugs, cosmetics, or devices that are "adulterated" or "misbranded." These concepts, which are defined in elaborate detail in the statute, are the functional equivalents of the more familiar terms, "unsafe" and "mislabeled."

Under this statutory scheme, the FDA's basic function was to discover and initiate court action against "adulterated" or "misbranded" products, and for many years this was our principal activity. Our competent field force conducted establishment inspections and market surveys, and laboratory examinations to discover illegal products. Upon discovering a violation, the Agency would initiate court proceedings which usually consisted of seizure of the illegal product, but might also include injunction or criminal prosecution. In short, the FDA functioned very much like the policeman on the beat, responding—and I think responding effectively—to violations that we encountered. But we increasingly found ourselves tied up in lengthy court battles, often litigating the same issue over and over again with different manufacturers. We also found that we sometimes were not able to discover a hazard or defect in a marketed product, and thus prevent harm before it occurred.

REFOCUSING OF FDA REGULATIONS

Since 1938, several developments have forced FDA to broaden and redirect its regulatory focus. Both Congress and the Agency came to recognize the limitations of after-the-fact, case-by-case enforcement. Moreover, during the past generation, the industries subject to FDA's jurisdiction grew dramatically in number and size and their products became more numerous and complex. Regulation of this burgeoning market principally by court action proved inadequate both because of the immensity of the task and because the issues increasingly called for the melding of the best possible science with sound legal practice.

In the years following 1938, Congress enacted several amendments to the basic Act which authorized the FDA to require scientific documentation before products could be marketed. The 1938 law granted the Agency authority to assure the safety of new drugs, prior to marketing. Congress gave FDA similar authority over pesticide chemicals in 1954, over food additives in 1958, and over color additives in 1960. And, in 1962, Congress gave us explicit authority to demand premarketing proof of effectiveness—in the form of well-controlled medical studies—for new drugs. These legislative changes enabled the FDA for the first time, to prevent the marketing of untested and unproved products, rather than having to react to violations after they occurred.

These amendments also had the effect of shifting to manufacturers the burden of supplying proof that the law's requirements that products be safe and perform as represented were, in fact, met.

During the past decade, it also became apparent that the statutory remedies of seizure, injunction and prosecution are not by themselves adequate to assure prompt and efficient removal of harmful products from the market. The Agency has responded by making increased use of product recalls, which place primary responsibility for removing hazardous products upon the companies involved in their manufacture or distribution, while FDA monitors performance.

FDA also became concerned that the failure of many manufacturers to comply with regulatory requirements was sometimes a result of our own failure to specify what the requirements were. We, therefore, began to promulgate regulations and provide guidance with the purpose of spelling out the responsibilities of industry. Among the products of this effort are our good manufacturing practice regulations, product standards, various voluntary compliance programs, and broadened educational activities. A central objective of our efforts has been to help industry fulfill its responsibility to manufacture and market safe products in the first place, thus freeing FDA to concentrate its resources on monitoring compliance with concrete standards established through administrative procedures.

Our present regulatory approach thus involves increased reliance on administrative standard-setting for product performance and manufacture. The process of standard-setting, and in fact all Agency activities, has become increas-

ingly important to the public and to the regulated industry. We have come to recognize the benefits of exposure of our decisionmaking to public scrutiny and of broadened involvement by interested persons and experts outside the Agency.

THE OVER-THE-COUNTER (OTC) DRUG REVIEW

Our current approach to regulation is best exemplified by a brief description of the regulatory program we have developed for assuring the safety and effectiveness of drugs sold over the counter. Commonly known as the "OTC Drug Review," this program illustrates the administrative procedures that we employ and how the public actively participates in our decisionmaking.

The OTC Drug Review was instituted to respond to the need to assure that nonprescription, or OTC, drugs are safe and effective. Because of a statutory exemption, many nonprescription drugs had been marketed without Agency approval of their safety or effectiveness. Using our time-honored, conventional procedures, the only way we could have taken action against these products was through individual lawsuits based on charges of "adulteration" or "misbranding." Such an undertaking would have been impossible because of the number of products involved—an estimated half million. Moreover, in the few cases the Agency did attempt, our legal challenge was frequently mooted by the company's decision to reformulate or relabel its product, forcing us to start over again.

Confronted with the prospect of prolonged and indecisive litigation, the FDA decided to develop a systemic industry-wide approach to regulating the entire class of OTC drugs. Our current approach involves the development of drug "monographs," in the form of regulations, which define safe and effective formulations, and proper labeling for entire categories of related products. The regulatory monograph for antacid and antiflatulent products was the first to become effective. Monographs have been proposed for nonprescription antimicrobial, laxative, antidiarrheal, antiemetic, and emetic products. Eventually monographs will exist for the entire class of nonprescription drug products. The result of this program will be to revolutionize the formulation and labeling of the medicines that are available to the consumer without a doctor's prescription.

The monographs are at the heart of the OTC drug review and the procedure by which these monographs are being developed embodies several novel features. Each monograph is initially developed by an advisory panel, comprised of medical experts from outside the Agency. These experts share their knowledge and experience and provide independent judgments in making recommendations respecting proper product formulation and labeling. Most meetings of the advisory panels are open to the public. Each panel listens to presentations and reviews documents submitted by scientists, consumers, and industry. Meetings are closed only when discussion will involve trade secrets or other confidential information, or during final committee deliberations.

Each OTC review panel includes, as members, a representative of consumer interests and a representative of industry nominated by the interested groups. These liaison representatives attend even the closed meetings of the panel. Their role, unlike that of the other panel members, is to represent a particular constituency and to transmit information between the panel and the groups they represent. The consumer and industry representatives participate in all panel deliberations but do not have a vote.

The OTC Review is structured to provide maximum opportunity for public input into the Agency's decisionmaking process. There are numerous stages at which interested parties can make known their views on the issues to be resolved. Any person may make an oral presentation to the expert review panel, or submit written documents that will be made a part of the record. After a panel makes its report evaluating individual ingredients and label claims for the entire class of products for which it is responsible—e.g., laxatives—the report is published in the *Federal Register* and given wide circulation. Any interested person has an opportunity to comment on the report. After considering these comments, the Commissioner publishes a tentative order, proposing a regulation, which is once more subject to public comment. In addition an opportunity is provided for oral argument in a public hearing before the Commissioner. At the conclusion of these procedures, the Agency publishes an order promulgating a final monograph, which is subject to immediate court review.

The procedure I have described is very open to the public. Thus interested persons and the general public are aware at all times of the direction in which

the Agency is heading. If consumers, scientists, or manufacturers disagree with a position that is being advanced, they are able to raise objections in a proper forum and at a time when their views have some prospect of influencing the ultimate decision.

The system also affords manufacturers advance notice of the changes that will be required of them. As a result, many companies have reformulated their products or revised their labeling to meet the requirements of a monograph even before it has taken effect. The high incidence of voluntary compliance with the OTC drug monographs that is occurring will greatly simplify the Agency's task of enforcing the regulations once they become final. However, because all manufacturers may not voluntarily comply with monographs, we will monitor performance by conducting inspections and sampling products. Where violations are found, we will undertake to enforce the monographs by means of judicial remedies: through seizure, injunction, or criminal prosecution.

In implementing this comprehensive regulatory program, the FDA, has faced a difficult problem of how to deal with products currently being marketed during the transition from the old "drug-by-drug" approach to the regulation by product class. Problems of transitional enforcement arise whenever a change is made in regulatory requirements, whether by statute or by administrative rule. We could have, of course, continued to pursue individual products through court actions, relying on the "adulteration" and "misbranding" provisions or attempting to expand the new drug requirements. As noted before, however, such an approach would have produced difficult, and in many cases pointless, litigation. Instead, the Agency decided that, during the period monographs were being developed, it would not challenge the marketing of individual products except when they posed a safety problem or represented an obvious fraud.

A final element of our regulatory approach to OTC drugs that should be of interest to your subcommittee is our effort to ensure that differing requirements are not imposed on the same products by different regulatory agencies. The FDA can control the formulation and labeling of nonprescription drugs, but it has no jurisdiction over their advertising, which is the responsibility of the Federal Trade Commission (FTC). To assure that the requirements of our two agencies are consistent, we have worked closely with the FTC since the inception of the monograph program. And the Commission now plans to adopt FDA's labeling requirements as standards for evaluating OTC drug advertising.

The OTC drug review encompasses what we believe to be the best of our administrative procedures: a well understood process of setting forth formal requirements to be met by an entire class of manufacturers, worked out in public, with ample opportunity for public participation. The process is open, candid, and effective. It allows the Agency the benefit of the best scientific expertise in the world, but results in practical regulations that can be efficiently enforced.

We hope to extend what we have learned in the OTC review to other product classes, and improve the process as we do so.

FDA PROCEDURAL REGULATIONS

Certain other important features of our administrative procedures have not been mentioned in our summary of the OTC Drug Review, but they merit brief discussion.

We have recently published a comprehensive set of regulations that lay out in great detail the rules governing all of the Agency's administrative practices and procedures. The regulations explain in clear, detailed fashion how new segments of the public can participate effectively in our activities. The new regulations describe clearly how citizens can petition the Agency. Any interested person may ask the Commissioner to issue, amend, or revoke a regulation or order, or take (or refrain from taking) any other form of administrative action. We have provided a standard form petition to make it easier for individuals to take advantage of this right. Under our regulations we must respond to any request for action within a reasonable period, and explain why we have or have not taken the action requested.

The regulations contain detailed procedures governing formal and informal rulemaking and adjudication. A feature particularly worth noting is the provision for establishment of public Boards of Inquiry. A person who, under the law, has a right to a formal trial-type hearing may elect instead to request a hearing before a Public Board of Inquiry. Members of a Board of Inquiry will

include nominees of the parties requesting its establishment. An adjudicatory hearing may drag on for months before issues are resolved, and trial-type procedures are not well suited for resolving complex scientific questions. A Board of Inquiry represents a novel way of permitting issues to be promptly resolved on their scientific merits rather than in an adversarial context. Our first Board of Inquiry will be convened soon to consider the safety of the artificial sweetener, Aspartame.

Our new procedural regulations also include mechanisms designed to assure the integrity of, and public confidence in, the Agency's decisionmaking processes.

For example, when an FDA employee talks with a private party about a pending regulatory matter, except when the purpose is solely to provide information, a written memorandum recording the substance of the conversation must be prepared by the employee. This requirement applies whether the conversation was by telephone or in a meeting. The memorandum becomes part of the public file of the case.

The regulations also require us to maintain two types of public calendars. The first is a weekly prospective calendar, which lists all public meetings, seminars, conferences, advisory committee meetings, public hearings, and other public proceedings of the Agency. In addition, we publish a retrospective calendar of private meetings held the previous week by all top Agency officials with persons outside the Federal Government.

FREEDOM OF INFORMATION REGULATIONS

A brief word is also in order concerning our Freedom of Information (FOI) regulations, which have been instrumental in opening FDA's records and files to public scrutiny. These regulations represent an effort to resolve publicly, and in advance, questions of disclosure that arise frequently under the statutes we administer, rather than making such decisions case-by-case, which would result in delay and inconsistency.

The Freedom of Information Act and our implementing regulations have produced some unexpected consequences. We currently are receiving upwards of 250 Freedom of Information requests per week many of them demanding enormous documents and raising complex issues. We estimate that the uncompensated cost of responding to these requests will exceed $700,000 this year. Furthermore, about 88 percent of the FOI requests that we receive are from private attorneys and industry. Only 12 percent come from the general press, consumers, health professionals, and scientists.

CONCLUSION

This latter trend, I confess, has been disappointing, but I am convinced that the policies we are striving to follow—stressing openness and public participation—strengthen the Agency, and increase public confidence in the integrity of our decisions.

It is essential that a Government regulatory agency operate in this fashion. The FDA is committed to procedures that permit us to deal openly and fairly with all persons affected by our decisions. We believe our new administrative procedures will improve communication and assure sound and expeditious disposition of the difficult and sensitive issues which the Agency continually confronts.

We are currently at work codifying the Agency's enforcement practices and procedures. This codification will include regulations relating to imports, criminal prosecution, recall and detention of products, publicity, and issuance of regulatory letters. These regulations will complete our efforts to paint a full, public picture of FDA's regulatory activities.

Mr. Chairman, my colleagues and I will be pleased to answer any questions you may have.

Senator ABOUREZK. The next witness is Marcia Greenberger, an attorney with the Center for Law and Social Policy.

TESTIMONY OF MARCIA GREENBERGER, ATTORNEY, CENTER FOR LAW AND SOCIAL POLICY, WASHINGTON, D.C.

Ms. GREENBERGER. My name is Marcia Greenberger, and I am an attorney with the Center for Law and Social Policy, a public interest

law firm located in Washington, D.C. I have represented a variety of women's rights organizations, consumer groups, and poverty groups before the Food and Drug Administration (FDA).

Therefore, I am particularly pleased to have the opportunity to discuss with this subcommittee the procedures used by the FDA in its administration of the Food, Drug, and Cosmetic Act.

My discussion today will reflect my experiences in representing consumer interests before the FDA.

The bulk of my practice has concerned FDA's regulation of drugs or cosmetics which have a particular impact on women. In this practice, I have been struck consistently with the scarcity of public interest representation before the agency.

In meetings, we have often been the only consumer representatives present, let alone participating. In contrast, dozens of drug manufacturer representatives regularly attend meetings and carefully monitor FDA activities.

Also, the number of comments on proposed FDA actions filed by consumer groups is usually far outweighed by those of industry.

There seems to be no question that on all levels FDA is receiving far less input from consumer groups than from industry. There are only a handful of consumer advocates who focus on the FDA, and generally they have few resources. They are unable to carefully monitor FDA, and as a consequence, positions may be taken by FDA without any analysis from consumers, while industry has been an active participant in every stage of the decisionmaking process.

I noticed in Commissioner Schmidt's testimony this morning a reference to the number of Freedom of Information Act requests which the agency has received. And Mr. Merrill indicated, I think, some disappointment at the few requests received by consumer groups and members of the public as compared to those from industry. I think that this is a prime example of the general problem that consumer groups face and consumers face. There are very few resources available to the consumers which will allow them to participate in agency monitoring. I think that the problem consumers face in requesting information from the Food and Drug Administration is basically a problem of inadequate resources. Consumers have very little staff available to them to determine the kind of information they need; to determine exactly the sort of questions they should be asking; and if they do request the information, they do not have the staff to review it.

Moreover, because of the procedures and regulatory posture adopted by FDA, this lack of consumer input is particularly serious. The regulatory process has been set up, and probably inevitably so, to pit consumer interests against industry interests. The advisory committees are a good example of the structure, as well as the public boards of inquiry, and other aspects of the procedural regulations which have been recently promulgated by the agency.

The advisory committees are comprised of experts in various areas, and as was just discussed, they play a very important role in advising the Food and Drug Administration in its regulatory responsibilities.

Moreover, under subpart D of the new procedural regulations, advisory committees may hold public hearings in place of formal evi-

dentiary hearings. These "unbiased" experts are supplemented by nonvoting members who represent industry and consumer interest. (See 40 Fed. Reg. secs. 2.330–2.333.)

I think that the structure of the advisory committee forms a prototype of the way the Food and Drug Administration views itself. The FDA acts as a balancer, and arbiter between consumer interests and industry interests. It is therefore very important to look at the information which is presented to FDA by the consumers and by the industry, to insure that consumer groups have the same degree of access, and the same ability to present information to the agency as does the industry.

Experience has shown that the consumer representatives simply lack the resources to present their views adequately and press vigorously for adoption of their positions. In contrast, the industry representatives have substantial resources behind them, which can be used for effective advocacy of industry interests.

It is rare, for example, that the consumer representatives have the resources to commission a study of relevant literature on a particular topic, consult with experts, or in any other way generate information to present to the advisory committee in support of the consumers' position.

In fact, the lack of information makes it difficult for the consumer representatives even to recognize problems which they should address.

Industry representatives, on the other hand, are able to marshal information which they can then present to the voting members of the committees. They have access to the resources of the industry whose products are at issue, and know full well the positions which will best serve their constituency.

An additional information barrier which limits still further the effectiveness of the consumer representatives is section 2.333(a)(2) of the new procedural regulations, which provides that nonvoting members of the advisory committees are not given access to trade secrets or confidential commercial or financial information. As was discussed earlier today, the definition of a trade secret, or confidential information, is very broad. In fact, the definition may include information concerning the safety and efficacy, for example, of drugs or other types of products, whether or not that information is gleaned from testing of human subjects.

Senator Abourezk. Can I interrupt just a moment?

I have read your statement, and the reason I am stopping you now is to ask what would be an appropriate remedy for what I recognize as a severe problem of consumers either not being organized enough or not having enough resources to find out whether they should inquire or what they should look into? How would you remedy that?

Ms. Greenberger. Well, I think there are a variety of possibilities. Just addressing consumer representatives and access to trade secret information, certainly I would think that at least in that narrow set of circumstances there should not be any problem in making such information available to those representatives as well as to members of the advisory committees. But we need to get to the broader issue of whether the consumers representatives or consumers in general can adequately present their interest.

I think that we are faced with a situation where we have to assume that industry and consumers will be pitted against each other, and we have to expect that it is up to the consumers themselves to present their viewpoints adequately. Then the issue arises as to whether consumers have adequate resources to be able to counter industry input. It must be kept in mind that industry has a great economic stake in the development and outcome of FDA policies. In contrast, each individual consumer has very little personal economic stake in the policies. Their economic stake comes as an aggregate of the entire population of all consumers. Therefore it is unrealistic to assume that individual consumers will provide the resources themselves to protect their interests.

I think one of the key ways of looking at a remedy to the solution might be through some sort of allocation of funds to the Food and Drug Administration which could support consumers' points of view and support the input that is necessary. At the moment, consumer representatives on the advisory committees are paid merely for their per diem expenses, as I understand it, and a fee for the actual time that they spend in advisory committee work. They are not given any funds to run literature searches, to consult with experts of their own, or to service consumer groups generally through setting out information about issues consumers should be aware of and participate in. I would think that one possible solution to the problems of consumers representatives would be a budgetary allocation to the Food and Drug Administration for the use by these consumer representatives. They would have a fund that they could draw on to supply necessary information to the advisory committees, to the Food and Drug Administration, and also to consumers. And, they would be able to give the consumers the resources necessary for the consumers themselves to present the kind of information they should to the FDA.

I think another possible use of agency funds would be in proceedings before the agency. There has been some allusion this morning to the different sorts of hearings, from a hearing before the Commissioner to a formal evidentiary hearing. Meaningful participation in any of these hearings is a very expensive prospect. I think attorneys' fees, expert witness fees, travel costs, and other out of pocket costs should be provided to participating consumer groups.

There have been various requirements placed upon citizens who wish to participate before the agency to prepare lengthy and complex papers, and in all cases, strict time limits are set. The only provisions in the procedural regulations that would give any financial recourse to consumer interests would be a waiving of service to all other participants in the hearing process. That would mean simply a saving of Xerox and mailing costs. That is certainly a step in the right direction, but it is a baby step.

Senator Abourezk. If the bill establishing the Consumer Protection Agency were passed, would representing consumers before FDA be one of the areas in which the Agency would become effective?

Ms. Greenberger. Yes; I think the Consumer Protection Agency could be very useful. But on the other hand, I would question whether the Consumer Protection Agency, with its broad mandate and the question of what it is funding would be, could take over the whole burden in the FDA.

I think there still would have to be some provisions for compensation of costs to private consumer groups who have particular studies and particular interests which they should be able to represent before the Food and Drug Administration.

I doubt whether the proposed Consumer Protection Agency could provide, in and of itself, enough of a counterweight to all the industry representation.

Senator Abourezk. Do you see as feasible a change in the mission and the objectives of the Food and Drug Administration which would make it oriented more toward representing consumers?

Ms. Greenberger. I do not think that is possible. And that is why in my statement I did take some pains to discuss the fact that there is at this moment, a pitting and I think an inevitable pitting between consumers and industry.

I think, in fact, that FDA is recognizing what is inevitable in regulatory agencies in Washington, despite what presumably was the purpose of regulatory agencies when they were first established. I think our experience has shown that the staff of regulatory agencies has a very difficult time in diversing itself from the industries which are being regulated, for any number of reasons. Many of the staff have been trained by the industry. Many intend to return to the industry when they have finished their public service. In addition, they are, I think, inundated with information from industry.

I basically would feel more comfortable with the recognition of an adversary system in agency proceedings, such as we recognize in courts. We do not expect judges normally to represent one side and have the other side represented by its own advocate.

I think that when that burden is placed on an agency, we have seen over the last 30 or 40 years, that the agency cannot handle it. It might be better for us to try to balance the adversarical interests—consumers and industry—and make sure that the two groups have the same sort of resources or comparable resources available to them so that they can each present their own point of view to FDA effectively.

Senator Abourezk. Please continue your statement.

Ms. Greenberger. We got to the core certainly.

I wanted to discuss some of the examples that I thought typified the problems with consumer input before the Food and Drug Administration. A superficial review of the procedural regulations can be misleading. I think that if one looks at the procedural regulations, one comes away with a sense of balance. Provision is made for a consumer representative, and an industry representative.

There is opportunity, as the Commissioner has said in his statement, for public participation in every stage. But when one goes behind that attempt at impartiality, one finds that the opportunity for input from the public most often is used and seized by the industries, and not by consumers.

There is one example that I thought would be useful to discuss which is not in my prepared statement. It deals with the private meetings that FDA holds with interested groups. Commissioner Schmidt stated today that one of the innovations of the procedural regulations would be to require a retrospective calendar and memoranda to be put in the files of any meeting. I think both of these requirements are certainly

useful—and are steps which should be taken. But when one looks more closely, I think it also indicates the disadvantage to which consumers have been placed.

Recently there was a meeting which was held between consumer groups and members of the staff of the Food and Drug Administration to discuss consumer labeling of drugs and cosmetics, information that would be made available on a particular drug packet, information to go to the consumer directly. This is an issue which has been of great interest to many consumer groups.

The meeting was published before it was held, and there was an industry representative present at the meeting along with the consumer groups.

However, several weeks earlier there was a meeting that appeared in the retrospective calendar of the Food and Drug Administration concerning cosmetics and the safety review program. The Food and Drug Administration has been considering having cosmetics reviewed for safety, and the industry would provide this review rather than have it done by an FDA panel. The consumer groups were quite concerned with this particular development. They learned in the retrospective calendar of a meeting that was held which was termed in the trade journals as a summit meeting between industry representatives and the Food and Drug Administration. Several consumer groups asked if they could be present for future meetings so that they would be able to discuss with the Food and Drug Administration and the industry representatives the wisdom of the procedures which were being developed with the cosmetic safety review procedure.

Commissioner Schmidt responded that the meetings should be held privately with the industry group, that he would be delighted to meet with the consumer groups separately, and that the memorandums of the meeting or the minutes of the meeting would be made available so that the consumer groups could review and make known to him at a later point any suggestions that they had.

I think on the surface that might seem appealing. But when one considers the practical problems that the consumers are faced with, they are really in a position of reacting rather than initiating new suggestions. If they are excluded from meetings with industry representatives, where the actual workings of a review commission would be discussed, and instead reduced to simply looking at memorandums, I think they are very much at a disadvantage.

And the idea that the Food and Drug Administration has developed of separate, private meetings with industry and separate, private meetings with consumer groups will also tend to put consumer groups at a disadvantage.

Of course, the fact is that some of the consumer group meetings have not in fact been private, and industry representatives who have been able to be present have raised some question about the evenhandedness of even this policy.

But in any event, in addition to many examples which I discuss in my prepared statement, this one also underscores some of the problems that consumers face.

I think if the retrospective calendar is going to continue, and consumer groups are going to be excluded from meetings with industry, at least there should be transcripts made of that meeting so that it will be on the public record. Memorandums can be misleading in nature.

Another example of the total imbalance between consumers and industry at work is a letter I recently received from the Bureau of Medical Devices and Diagnostic Products.

The letter stated that the FDA would no longer send copies of minutes of advisory panel meetings to all interested persons. Instead, a list of four industry and consumer groups were provided, with the suggestion that these groups would receive the minutes and send copies to their affiliates.

The list contained three industry trade associations and the Nader-related Health Research Group. Aside from the obvious problem that that three industry groups are listed and only one consumer group, the crucial fact is that Health Research Group has no affiliates.

Moreover, it is a relatively small organization that hardly has the resources to duplicate minutes for all interested consumers and consumer groups.

In addition, the letter provided a list of industry representatives on the panels, with the suggestion that industry members contact these representatives for information concerning the agenda of the panels. No list of consumer representatives was provided, and even if it were, as I discussed, I have serious questions about the ability of the consumer representative to adequately service consumers.

As a result, consumer groups are shut off even more from the everyday flow of information which would alert them to issues they should address.

Another disturbing element which I would like to discuss is the public boards of inquiry. These boards of inquiry under the new procedural regulations are to hold hearings concerning "any matter, or class of matters, of importance pending before the Food and Drug Administration" (40 Fed. Reg. sec. 2.200(a)).

The board may act as an administrative law tribunal, and replace a formal evidentiary public hearing. The board consists of three members—chosen by the Commissioner from lists of five names each. The first member is selected from lists submitted by the FDA Bureau Director, or nonparties, involved in the issue, the second from lists submitted by parties, and the third from any source the Commissioner chooses. The regulations also provide that a private party may veto any FDA employee as a member of the board.

In short, the concept of FDA as arbitrator between competing groups is applied again. In this circumstance, however, the actual decisionmakers are representatives of these competing groups.

Moreover, there are serious questions as to the wisdom and propriety of allowing private parties to select the initial decisionmakers in their case, when the board is ostensibly an arm of FDA.

The entire concept of a board of inquiry chosen in this manner is not only a departure from usual administrative law practices, but directly serves the interests of industry while excluding participation of consumers. The extraordinary rights given to participate in the selection of at least one board member, and to veto FDA employees, are rights given only to parties.

FDA has defined parties in such a way to exclude consumer groups in most instances. Therefore, the composition, and presumably the decisions, of these boards will not adequately reflect consumer interests.

In the next section of my statement, I discuss the need for attorney fees and the expert witness costs which we have already reviewed. I

would like to go on and discuss some of the problems with the FDA procedural regulations which are common to all groups with interests before the Food and Drug Administration.

At the outset, I would like to say that the sweeping new procedural regulations certainly have benefits, in that information concerning proper practices is provided and is easily obtainable. However, there are some serious problems with the regulations as well.

First, despite their broad nature, encompassing many changes in past practices, the regulations were issued in final form. It would have been far preferable had FDA followed the usual practice of issuing regulations in proposed form, with an opportunity to the public to comment and a consideration of those comments before the final version was adopted.

Mr. Merrill and Commissioner Schmidt stated earlier that they were desirous that procedures be applied immediately, and thought that many of the provisions were so needed that they were not going to wait for a comment period before they adopted the regulations in final form.

I would agree that there are certainly elements which might have made sense to have adopted immediately, such as the example given by Commissioner Schmidt of requiring memoranda of meetings of private parties. I, of course, would prefer that there be something more detailed than memoranda. But regardless, I think the concept is a good one. But I think a distinction should be drawn between the regulations such as that type which are relatively clear-cut, and easy to see the pros and cons, and I would think relatively noncontroversial, as compared to something such as a public board of inquiry, which is a very new concept, and which I would think raises serious public policy questions. It should be considered very carefully, with the advantage of public input, to arrive at a good procedure.

The argument that it is important to get that sort of regulation into effect immediately is something that I do not understand.

To establish and hold a hearing before a board of inquiry would be relatively time consuming. And therefore, I think what we are talking about in setting up boards of inquiry or other types of hearing procedures is something with very long range consequences which, granting Commissioner Schmidt and Mr. Merrill's statement that they might be changed and modified later depending on public comment, would have locked in many parties in adjudicating their rights over a long period of time despite intervening changes.

I think that that sort of regulation should not have been issued in final form. The general broad policy regulatory provisions which represented departure from previous FDA policy should have been open to public comment.

Second, the regulations themselves set a disturbing tone of requiring persons or groups to adhere to strict deadlines, and to exhaust numerous complex and costly administrative steps before challenging an FDA action in court. Yet no time limits are set within which FDA must respond.

As a result, court review may be postponed for years because of FDA inaction. In fact, in the discussion published in the Federal

Register preceding the regulations, it is stated that many petitions will not be acted upon for long periods of time because FDA may consider them of "low priority."

Yet FDA has required a petition to be filed, the petition be acted upon, and a request for a stay of an adverse FDA decision, before a party may go into court. When the health and safety of the public is at stake, FDA's unfettered ability to delay decisionmaking and thereby preclude judicial review, cannot be tolerated. Instead, FDA should be required to take formal action within fixed time limits.

There is a second general point about the regulations, which may be of particular interest to this committee.

There are a variety of statements made throughout the regulations dealing with FDA policy on such issues as exhaustion of administrative remedies, burden of proof and standing in court, which are decisions normally, and I think properly, made by judicial bodies, and not by the Food and Drug Administration.

To the extent that these regulations are viewed as merely an explanation of FDA's interpretation of the law, rather than any sort of interpretation that is entitled to deference, they may be appropriate.

Unfortunately, they are often housed in more strong and definitive terms than I think they are entitled to be.

Finally, FDA makes no requirement that transcripts be made of all advisory committee meetings. Instead section 2.314 provides that each committee will decide whether or not to make a transcript. Given the importance of committee meetings, however, and the simple nature of making taped or transcribed transcripts, reliance on minutes cannot be justified. Without a transcript, neither FDA officials nor the general public is able to judge the reasoning upon which recommendations are based.

In conclusion, as a representative of consumer interests, I am disturbed by the imbalance in the presentation of information which now exists in the FDA. Industry is able to present its views, with more than sufficient resources available. Not only are individual companies carefully monitoring FDA action which affects their interests, but trade associations as well scrutinize FDA on a daily basis.

In contrast, there are very few existing consumer groups who are able to engage in any monitoring of FDA at all. In most cases, they are faced with the choice of focusing on particular and discrete problems, or of making a surface review of FDA activities. They are often unable to provide assistance to consumer representatives in FDA advisory committees, and in turn these representatives lack the resources to service the consumer groups adequately.

FDA's decisionmaking processes are structured in such a way that, perhaps inevitably, industry is pitted against consumers.

As a result, the disadvantages under which consumers must operate are particularly serious. Steps should be taken to redress the imbalance, and provide consumer groups with the resources to defend their interests.

Senator Abourezk. Section 2.512 provides that a regulatory hearing may be conducted in private or may be a public hearing as determined by the party requesting the hearing. Do you have any comment on inclusion of such a provision?

Ms. GREENBERGER. I think that gets in to the whole problem of the Freedom of Information Act and the type of information which is made available and which is not made available to the public. Especially where an issue of allowing a drug, for example, to be marketed, is being discussed, many of the various important pieces of information presumably under present FDA actions are not made public. I think obviously it is a problem. I have not had very much experience in dealing with the Freedom of Information Act, and in studying the nature of the trade secrets requirements. I believe that the health research group, which has submitted a prepared statement to this committee,[1] will be discussing at some length the Freedom of Information Act requirements that the Food and Drug Administration has set forth, and the particular provisions of their secrecy which are either required or discretionary with the Commission. Hopefully they will be able to elucidate some of those problems better than I.

Senator ABOUREZK. In your dealings with the FDA in rulemaking and hearing situations, has it been your experience that sufficient time has been provided for making submissions and preparing for participation in hearings?

Ms. GREENBERGER. Well, I think again I have to keep harping back to the same problem that consumer groups face. In preparing for hearings often they have not had the number of years of dealing with a particular issue that the industry has had, since the industry from the start has been developing a plan to get the particular drug or whatever approved. Setting up a very stringent, and under these regulations, extremely short, time periods, will work to the particular disadvantage of consumer groups.

And I think there is also quite a bit of inflexibility in these procedures concerning the extension of time periods, and also the extremely heavy burdens placed on all participants to come forward within the time periods with all of the evidence that they intend to produce. I think that works a particular hardship to consumers, although I understand that industry representatives are concerned as well with those strict time periods and heavy burdens placed upon the parties.

Senator ABOUREZK. What about the new procedures? What do they do in the situation that we are talking about?

Ms. GREENBERGER. I think they exacerbate the problem if they make any changes at all, in that they require, for instance under the formal hearings provisions which are discussed earlier, very stringent time periods of 30 days after the Commission has taken particular actions, for a request for a hearing to be filed. And if there is such a request, as I think Mr. Tobias correctly pointed out, it requires a virtual showing of the probability of success before the hearing is ever held, with no provision for extension of time. And those sort of requirements would involve consumer groups as well as private industry.

Senator ABOUREZK. In your review of the new regulations on administrative practices and procedures, have you discovered any other areas that present particular problems for public interest and consumer groups in dealing with FDA?

Ms. GREENBERGER. I think the major problems are the ones I discussed in my testimony. And I do want to underscore for a moment,

[1] See statement of Anita Johnson, Public Citizen's Health Research Group, p. 68.

the problem of the lack of time constraints which FDA has placed on its own action. I think that has disturbed the consumers interests as well as the industry. There have been in the past experiences that I have had with the Food and Drug Administration requiring submissions to be made within a very short period of time, and we have complied with that short period of time, and many months have gone by with no action taken on the part of the Food and Drug Administration. And if the Food and Drug Administration intended, as certainly it seems clear they intended under this procedural regulation, to require a variety of remedies to be exhausted by the public before court review is acceded to by the Food and Drug Administration, I think it is encumbent upon the agency to give itself stricter time periods as well.

Senator ABOUREZK. Have you had an opportunity to review the new public information regulations? If so, have you discovered any areas that present particular problems for public interest and consumer groups in attempting to obtain information from FDA?

Ms. GREENBERGER. Unfortunately, I have reviewed them, but I have had very little experience in dealing with the Freedom of Information Act, and I'm hopeful that the health research group will deal fully with that when they make their representation to this subcommittee.

Senator ABOUREZK. Ms. Greenberger, those are all the questions I have at this point. I want to express my thanks to you for an excellent statement and an excellent discussion. Thank you very much.

Ms. GREENBERGER. Thank you.

[The prepared statement of Ms. Greenberger follows:]

PREPARED STATEMENT OF MARCIA GREENBERGER

My name is Marcia Greenberger, and I am an attorney with the Center for Law and Social Policy, a public interest law firm located in Washington, D.C. I have represented a variety of women's rights organizations, consumer groups and poverty groups before the Food and Drug Administration (FDA). Therefore, I am particularly pleased to have the opportunity to discuss with this Subcommittee the procedures used by the FDA in its administration of the Food, Drug and Cosmetic Act. My discussion today will reflect my experiences in representing consumer interests before the FDA.

I. BACKGROUND

The bulk of my practice has concerned FDA's regulation of drugs or cosmetics which have a particular impact on women. In this practice, I have been struck consistently with the scarcity of public interest representation before the agency. In meetings, we have often been the only consumer representatives present, let alone participating. In contrast, dozens of drug manufacturer representatives regularly attend meetings and carefully monitor FDA activities. Also, the number of comments on proposed FDA actions filed by consumer groups is usually far outweighed by those of industry.

There seems to be no question that on all levels FDA is receiving far less input from consumer groups than from industry. There are only a handful of consumer advocates who focus on the FDA, and generally they have few resources. They are unable to carefully monitor FDA, and as a consequence, positions may be taken by FDA without any analysis from consumers, while industry has been an active participant in every stage of the decision making process.

Moreover, because of the procedures and regulatory posture adopted by FDA, this lack of consumer input is particularly serious.

II. FDA CONCEPTION OF ITS REGULATORY ROLE

Rather than viewing itself as a protector of consumer interests, FDA seems to see its role as arbitrator between industry and the public. This regulatory

attitude is reflected in the structure of its advisory committees, public boards of inquiry, and other aspects of the procedural regulations recently promulgated by FDA, 40 Fed. Reg. § 1.1a et seq., 22950–23046 (May 27, 1975).

A. Advisory Committees

An examination of FDA's use of advisory committees is particularly instructive in understanding the very core of FDA's approach to regulation. Advisory committees, each comprised of experts in a variety of areas, have been established to aid FDA in its regulatory responsibilities. Moreover, under Subpart D of the new procedural regulations, advisory committees may hold public hearings in place of formal evidentiary hearings. These "unbiased" experts are supplemented by nonvoting members who represent industry and consumer interests. See 40 Fed. Reg. §§ 2.330–2.333.

FDA has virtually conceded that outside representatives are needed to present consumer positions. It becomes important, therefore, to review the practical workings of the advisory committee system as it now exists to determine whether those positions are being adequately presented.

Experience has shown that the consumer representatives simply lack the resources to present their views adequately and press vigorously for adoption of their positions. In contrast, the industry representatives have substantial resources behind them, which can be used for effective advocacy of industry interests.

It is rare, for example, that the consumer representatives have the resources to commission a study of relevant literature on a particular topic, consult with experts, or in any other way generate information to present to the advisory committee in support of the consumers' position. In fact, the lack of information makes it difficult for the consumer representatives even to recognize problems which they should address.

Industry representatives, on the other hand, are able to marshall information which they can then present to the voting members of the committees. They have access to the resources of the industry whose products are at issue, and know full well the positions which will best serve their constituency.

An additional information barrier which limits still further the effectiveness of the consumer representatives is section 2.333(a)(2) of the new procedural regulations, which provides that nonvoting members of the advisory committees are not given access to trade secrets or confidential commercial or financial information. As a result of this provision, consumer representatives are barred from reviewing basic information which presumably is key to the advisory committee's decision. The industry representatives, however, would most likely be aware of such information in many circumstances.

A concrete example of the total imbalance between consumers and industry at work is a letter I recently received from the Bureau of Medical Devices and Diagnostic Products. The letter stated that the FDA would no longer send copies of minutes of advisory panel meetings to all interested persons. Instead a list of four industry and consumer groups were provided, with the suggestion that these groups would receive the minutes and send copies to their affiliates.

The list contained three industry trade associations, and the Nader-related Health Research Group. Aside from the obvious problem that three industry groups are listed and only one consumer group, the crucial fact is that Health Research Group has no affiliates. Moreover, it is a relatively small organization that hardly has the resources to duplicate minutes for all interested consumers and consumer groups.

In addition, the letter provided a list of industry representatives on the panels, with the suggestion that industry members contact these representatives for information concerning the agenda of the panels. No list of consumer representatives was provided, and even if it were, consumer representatives do not have the resources to adequately apprise interested consumers of FDA activities. As a result, consumer groups are shut off even more from the everyday flow of information which would alert them to issues they should address.

B. Public Boards of Inquiry

The new procedural regulations also provide for a public board of inquiry to hold hearings concerning "any matter, or class of matters, of importance pending before the Food and Drug Administration." 40 Fed. Reg. § 2.200(a) at 23.010. The Board may act as an administrative law tribunal, and replace a formal evidentiary public hearing.

The Board consists of three members—chosen by the Commissioner from lists of five names each. The first member is selected from lists submitted by the FDA bureau director, or nonparties, involved in the issue, the second from lists submitted by parties, and the third from any source the Commissioner chooses. The regulations also provide that a private party may veto any FDA employee as a member of the Board.

In short, the concept of FDA as arbitrator between competing groups is applied again. In this circumstance, however, the actual decision-makers are representatives of these competing groups.

Moreover, there are serious questions as to the wisdom and propriety of allowing private parties to select the initial decision-makers in their case, when the Board is ostensibly an arm of FDA. The entire concept of a board of inquiry chosen in this manner is not only a departure from usual administrative law practices, but directly serves the interests of industry while excluding participation of consumers. The extraordinary rights given to participate in the selection of at least one Board member, and to veto FDA employees, are rights given only to parties. FDA has defined parties in such a way to exclude consumer groups in most instances. Therefore, the composition, and presumably the decisions of these Boards will not adequately reflect consumer interests.

III. CONSUMERS ARE UNABLE TO PROTECT THEIR INTERESTS THROUGH OTHER MEANS

Consumers not only receive little protection from consumer representatives on advisory committees or boards of inquiry, but they also are unable to advance their interests through other channels. In the new procedural regulations, FDA sets out elaborate mechanisms for agency review and alternatives of full evidentiary hearings, public hearings before a public board of inquiry, advisory committees or the Commissioner. In the case of full evidentiary hearings and public board of inquiry hearings, heavy burdens are placed on any group which wishes to participate in these proceedings to prepare lengthy and complex papers, and in all cases, strict time limits are set.

FDA recognizes the expense attendant to participation in such proceedings, and the regulations provide for "in forma pauperis" participation. Parties who show indigency and/or a public interest in their participation may avoid the costs of service of all papers they file to all participants. However, the costs of reproducing papers is only a minor expense involved in effective participation.

Expert witness fees, travel costs, attorneys' fees, costs of transcripts and the like all must be borne by serious participants in many of these proceedings. And it is the consumer groups who are least able to bear the expense of such participation.

Recent court decisions have indicated the reluctance of courts to allow the recovery of such costs, either in litigation or in agency proceedings, without a clear congressional mandate. See, *e.g.*, *Alyeska Pipeline Service Co.* v. *Wilderness Society*, 95 S.Ct. 1612 (1975) and *Turner* v. *FCC*, —— F. 2d ——, Nos. 74–1298, 74–1299, D.C. Cir. June 23, 1975). Moreover, FDA has consistently used the excuse of unclear statutory authority when refusing to adopt positions urged by consumers. Given the conservative nature of FDA when consumer interests are at stake, a statutory provision expressly providing for the award of such expenses is essential, if Congress is concerned that consumer participation be maximized in FDA proceedings.

Congress has recognized the importance of institutionalizing public participation before the Federal Trade Commission, and recently provided for the recovery of costs and attorneys' fees under circumstances which could be applied appropriately to the FDA, as well as other agencies. See Magnuson-Moss Warranty–FTC Improvement Act, P.L. 93–637, 93rd Cong., 2nd Sess. The extension of such a provision to FDA would make possible the beginnings of a strong, established consumer force. With the chance of financial remuneration for services rendered, consumer advocates could continuously review FDA activities and develop the necessary expertise to provide a meaningful counterforce to industry.

IV. PROBLEMS OF FDA PROCEDURES COMMON TO ALL GROUPS WITH INTERESTS BEFORE FDA

The sweping new procedural regulations certainly have benefits, in that information concerning proper practices is provided and is easily obtainable. However, there are some serious problems with the regulations as well.

First, despite their broad nature, encompassing many changes in past practices, the regulations were issued in final form. It would have been far preferable had FDA followed the usual practice of issuing regulations in proposed form, with an opportunity to the public to comment and a consideration of those comments before the final version was adopted. Although a comment period is provided for these regulations, presumably they are being applied at present, and the impact of comments is unclear.

Second, the regulations themselves set a disturbing tone of requiring persons or groups to adhere to strict deadlines, and to exhaust numerous complex and costly administrative steps before challenging an FDA action in court. Yet no time limits are set within which FDA must respond. As a result, court review may be postponed for years because of FDA inaction. In fact, in the discussion published in the Federal Register preceeding the regulations, it is stated that many petitions will not be acted upon for long periods of time because FDA may consider them of "low priority." Yet FDA has required a petition to be filed, the petition be acted upon, and a request for a stay of an adverse FDA decision, before a party may go into court. When the health and safety of the public is at stake, FDA's unfettered ability to delay decision-making and thereby preclude judicial review, cannot be tolerated. Instead, FDA should be required to take formal action within fixed time limits.

Finally, FDA makes no requirement that transcripts be made of all advisory committee meetings. Instead section 2.314 provides that each committee will decide whether or not to make a transcript. Given the importance of committee meetings, however, and the simple nature of making taped or transcribed transcripts, reliance on minutes cannot be justified. Without a transcript, neither FDA officials nor the general public is able to judge the reasoning upon which recommendations are based.

V. Conclusion

In short, as a representative of consumer interests, I am disturbed by the imbalance in the presentation of information which now exists in the FDA. Industry is able to present its views, with more than sufficient resources available. Not only are individual companies carefully monitoring FDA action which affects their interests, but trade associations as well scrutinize FDA on a daily basis.

In contrast, there are very few existing consumer groups who are able to engage in any monitoring of FDA at all. In most cases, they are faced with the choice of focusing on particular and discrete problems, or of making a surface review of FDA activities. They are often unable to provide assistance to consumer representatives in FDA advisory committees, and in turn these representatives lack the resources to service the consumer groups adequately.

FDA's decision making processes are structured in such a way that, perhaps inevitably, industry is pitted against consumers. As a result, the disadvantages under which consumers must operate are particularly serious. Steps should be taken to redress the imbalance, and provide consumer groups with the resources to defend their interests.

Senator Abourezk. Next we have a panel composed of Stanley Temko, of Covington & Burling; Joel Hoffman, of Wald, Harkrader & Ross; Raymond McMurray of McMurray & Pendergast; and Jane Lang McGrew, of Steptoe & Johnson.

Welcome to the subcommittee.

Mr. Temko, you may proceed.

TESTIMONY OF STANLEY L. TEMKO, COVINGTON & BURLING

Mr. Temko. Thank you, Senator. Each of us has a statement. We haven't really synchronized them, and we address some of the questions in varying ways. We talked it over with Mr. Tobias, and he suggested that each of us go through his statement and summarize, and then you might want to question all of us together.

Senator Abourezk. As is usual, if you are the last scheduled witness, we run out of time. I apologize for that. So I think you can at least start and perhaps return later if that is all right with you.

Mr. Temko. Fine. And I assume our statements will all be included in the record.

My name is Stanley Temko. I practice law here in the District as a member of the firm of Covington & Burling.

It is my understanding that all of us at the table were invited to participate in these hearings as lawyers in private practice. I am one who deals often with the Food and Drug Administration as well as other Federal agencies. And I'm happy to be here and to have the opportunity to express my personal views.

At the outset I wish to say that I enjoyed hearing the FDA's presentation this morning. It is good to have the agency afforded an opportunity to present to a congressional committee its views regarding some of its regulatory philosophies and policies. All too often FDA seems to be at hearings on both sides of the Capitol at which it is criticized regarding specific matters, but is not given an opportunity to state its position on basic issues of regulatory policy.

In that connection, I continue to be surprised that the FDA succeeds in doing as much as it does, although it does not accomplish as much as it should or do as effective a job as one would hope. In view of all the agency's difficult problems, Boswell's story about Dr. Johnson seems apposite. In commenting on a dog walking on its hind legs, Dr. Johnson said, "It is not done well; but you are surprised to find it done at all."

The Commissioner mentioned this morning, I recall, that perhaps 80 percent of his time in the last few months was taken with preparation and attendance at hearings. It is pretty difficult to see how you can run an agency if you are up here testifying all the time.

I take it that the principal concern of the subcommittee today is whether the procedures employed by FDA in its programs, with particular attention to the rules and regulations promulgated by the agency, are consistent with the requirements established by Congress. I have no doubt that many of FDA's innovative programs and procedures reflect the agency's judgment that those are the only methods by which it can successfully perform its responsibilities. On the other hand, I believe it is fair to say that many of those methods are based, not upon what the Food, Drug, and Cosmetic Act and other congressional enactments provide, but rather upon what the Food and Drug Administration would like them to provide.

I submit that it is of particular importance for the subcommittee to focus on this point in connection with the Food and Drug Administration. The reason for this is that the courts, with their proper concern for the health and well-being of our citizenry, cannot—except in isolated cases—realistically be expected to impose significant restrictions upon FDA's efforts to stretch and expand its authority. This is so even where FDA asserts that it has authority despite the absence of any apparent basis for it in the statute, and even in many cases where the courts are disturbed by the ways in which the FDA has disregarded procedural and other rights.

This is not to say that the courts will not on occasion strike down specific FDA actions. The point is that every instance of FDA's efforts to overreach its authority cannot be brought before the courts. Only occasional instances can be rectified by judicial action. This should not be surprising—it's the opposite side of the coin to FDA's position alluded to by the Commissioner this morning, that FDA cannot enforce the statute on a case-by-case basis through the courts.

As a result, unless the Congress implements its role as legislator and carefully reviews FDA's exercise of its authority, there will be no genuine limitations upon the agency's discretion. Until Congress examines basic FDA programs in greater detail than it now does, and imposes legislative restrictions upon inappropriate programs or procedures, the agency will continue to be free to legislate its own responsibilities.

This morning I want to mention two situations to illustrate this basic point. Both matters, incidentally, have been alluded to by the agency in its testimony today.

The first relates to FDA's program for review of over-the-counter drugs, which Commissioner Schmidt discussed earlier. The second concerns FDA's actions in connection with the statutorily mandated opportunity for a hearing in such situations as FDA's proposed withdrawal of a drug from the market or the agency's refusal to approve a new drug for marketing.

Let me turn to the OTC drug review. As the Commissioner has explained, the FDA determined that the only practical way to review the entire market of OTC product to determine their safety and efficacy was through a review by product classes, and not on a case-by-case basis. Consequently, the FDA began in 1972 to review all OTC products through a series of over-the-counter advisory committees, each dealing with a designated class of products.

I personally agree that the only practical way to review the entire OTC market, comprising thousands of OTC products, was by some program along the lines adopted by FDA. Although many people, including a number of other lawyers in private practice, take the view that a case-by-case basis could be used, to my mind it is not nearly as effective or sensible as a class approach. Necessary though it was, however, the OTC monograph system was not foreshadowed by any provision of the Food, Drug, and Cosmetic Act. In fact, it represented a fundamental departure from the case-by-case regulatory system embodied in the new drug provisions first enacted by Congress in 1938 and amended in 1962. The simple truth is that the OTC review was manufactured out of whole cloth.

For example, the Food, Drug, and Cosmetic Act contains detailed provisions governing judicial review of FDA actions respecting new drug applications and various other agency determinations.

The interesting point is that the act contains no provisions whatever for review of determinations made under the OTC review. It is completely silent. To resolve the problem, FDA was compelled to assert that review in a district court, under the general provisions of the Administrative Procedure Act, would be appropriate.

Such makeshift procedures, built from scratch by the agency and superimposed on the statutory framework created by Congress, might be justifiable as a short-term expedient to resolve a temporary problem. But the OTC review is not an emergency measure. It is a fundamental new regulatory scheme that will, for over-the-counter products, supplant the procedures specified by the act. A regulatory system of its significance and long-term impact should have been the subject of congressional deliberation. Its basic provisions should be embodied in the statute; they should not be controlled by regulations that FDA can amend or revoke at any time through informal rulemaking.

I mention that you are running into a similar situation in the recent FDA announcement that there will be a system of old drug monographs for prescription drugs. This again, like the OTC review, is a new regulatory program. It may be a commendable one, but the FDA should not be permitted to establish it by fiat. This is the type of basic program, whatever its content, that should be proposed to and enacted by the Congress. It should not be left to FDA rules and procedures.

The second example that I wanted to mention was the FDA's treatment of the provisions of the act providing for an opportunity for a hearing. There are various provisions in the act, some providing for an absolute hearing and others providing an opportunity for a hearing. But it is clear that the act, in such provisions as sections 505 and 507, contemplates that where factual issues are disputed, or there are clear differences of scientific judgment, those differences must be resolved at a hearing. In recent practice, however, the agency has steadfastly sought to resolve all factual issues and to deny hearings in cases where, by any proper standard, it is apparent that a hearing is required.

General Counsel Merrill this morning mentioned that many other agencies are using shortcuts or procedures to cut down on hearing time. This is true. But these agencies are working within the hearing framework.

One of the interesting things I find is that you can take an experienced administrative lawyer—I have done this with several of my partners—and expose him to a situation before the FDA in which we are seeking our right to a hearing. Invariably, they will express surprise and state that they cannot see how a hearing can properly be denied.

You would get a hearing in other Federal agencies. As I say, these are experienced administrative lawyers. But they have not been practicing before the FDA.

I recognize the FDA's pragmatic interest in trying to eliminate hearings. It apparently feels that such hearings require too much time, and that its other work would be slowed by the diversion of scarce manpower.

In addition, the FDA is probably influenced by the fact that its hearings in past years have sometimes been unduly protracted, and indeed have served as illustrations of what administrative hearings should not be.

But the fact is that this results from the way FDA conducted the hearings. It should not go to the basic question of whether there is a right to a hearing.

I read some days ago that Commissioner Schmidt had said in an interview that the Food, Drug, and Cosmetic Act should be amended to permit FDA to remove a drug from the market without a hearing. He made a similar statement here today. Unfortunately, FDA has for the past several years sought to administer the law as if Congress had already amended it to eliminate the hearing requirement. Such disregard of statutory provisions is not the proper answer to the agency's administrative difficulties. Two preferable solutions exist. First, FDA could seek to improve its hearing procedures and the manner in which hearings are conducted. Second, if the agency believes that the hearing requirement should be eliminated in some

situations, it should seek appropriate legislation and justify its position to Congress.

As a practical matter, FDA's studied policy of circumventing the hearing requirements of the law probably cannot be reversed by the courts. The bulk of the agency's decisions are not reviewed by any court. In recent months, the agency has been criticized for its disregard of congressionally mandated procedures on a number of occasions, but judicial efforts to limit the agency's discretion and assure petitioners their statutory hearing rights have had little discernible effect on general FDA policy.

In the next few pages of my statement I summarize several of the recent leading cases on FDA hearing questions, one a Supreme Court case, and three or four court of appeals decisions. You can see from the discussion, and the quotations from the court opinions, that the courts are somewhat frustrated at the FDA's continued disregard of the hearing requirements. The cases in the Supreme Court were cited by the FDA witnesses this morning as giving the agency a blessing for its current procedures. As I mention, in my discussion of the *Hynson* case, the Supreme Court did uphold in principle the invocation of administrative summary judgment in some situations, where it appears conclusively from the face of the pleadings that the application cannot succeed. But in the case itself, the Supreme Court ordered that a hearing be given Hynson. I can tell you that there are many situations since Hynson involving administrative petitions before the agency, where there is far clearer basis for a hearing than in Hynson, and a hearing has been denied. And there was clear basis for a hearing in Hynson and the FDA had simply denied the matter out of hand. So while FDA talks about the Supreme Court decisions, it does not follow them.

As I mentioned, in my statement, I also discuss three or four court of appeals decisions which again take issue with the agency in not granting a hearing. I want to mention the most recent. This is the *Edison Pharmaceutical* case in the Court of Appeals for the District of Columbia Circuit, where the court concludes: "In our eyes this failure to grant a hearing to any applicant casts doubt upon the good faith we would ordinarily impute without question to a decision of the Commissioner."

This conclusion follows the court's observation that for years the FDA had not granted any hearings at all.

Conceivably, the extensive procedural regulations recently promulgated by FDA may presage a new respect for the procedural requirements imposed by Congress. In the absence of some congressional prodding, however, I am not confident that this will be the case, for the new regulations reflect the old policy. They seek in many cases to supplant the hearings provided for by Congress with new procedures, never the subject of legislative deliberation, that will substantially diminish the rights of regulated persons. Similarly, the regulations appear to place additional requirements on obtaining a hearing that find no place in the statute.

As a result, I must return to my basic point—if FDA wants to change the procedures set forth in the statute, it should do so by proposing legislation to Congress, and not by disregarding Congress' instructions.

It seems to me that it would be well if we saw more hearings at FDA

and at least somewhat fewer FDA hearings in Congress. In my own personal view, at least some of the extensive congressional hearings in which FDA has been almost constantly engaged in recent years do not justify the extreme demands in preparation and attendance that they place upon senior FDA officials. I frequently wonder how necessary and important decisions can be made on a day-to-day basis at FDA when its principal officials are running from one congressional hearing room to another to review again and again, not general policy matters, but particular factual situations of limited importance and interest. By contrast, an occasional review—perhaps on an annual basis—by a committee such as this of basic questions of FDA policy and the FDA record in dealing with the legislation enacted by Congress would be fruitful and of continuing value.

Thank you.

[The prepared statement of Mr. Temko follows:]

PREPARED STATEMENT OF STANLEY L. TEMKO

I am Stanley L. Temko. I practice law here as a member of the firm of Covington & Burling. It is my understanding that I was invited to participate in these hearings as a lawyer in private practice who often deals with the Food and Drug Administration as well as other federal agencies. I am happy to do so and to express my own personal views to the Committee.

At the outset, I wish to observe that the presentation of Commissioner Schmidt and FDA's General Counsel, Richard Merrill, was of considerable interest. I am personally very pleased that FDA has been afforded this opportunity to present to the Subcommittee its views regarding its regulatory philosophy and policies. All too often, FDA seems to be at hearings on both sides of the Capitol at which it is criticized regarding specific matters, but is not given an opportunity to state its position on basic issues of regulatory policy.

In that connection, I continue to be surprised that the FDA succeeds in doing as much as it does, although it does not accomplish as much as it should or do as effective a job as one would hope. In view of all of the agency's difficult problems, Boswell's story about Dr. Johnson seems apposite. In commenting on a dog walking on its hind legs, Dr. Johnson said, "It is not done well; but you are surprised to find it done at all."

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I submit that it is of particular importance for the Subcommittee to focus on this point in connection with the Food and Drug Administration. The reason for this is that the courts, with their proper concern for the health and well-being of our citizenry, cannot—except in isolated cases—realistically be expected to impose significant restrictions upon FDA's efforts to stretch and expand its authority. This is so even where FDA asserts that it has authority despite the absence of any apparent basis for it in the statute, and even in many cases where the courts are disturbed by the ways in which the FDA has disregarded procedural and other rights.

This is not to say that the courts will not on occasion strike down specific FDA actions. The point is that every instance of FDA's efforts to overreach its authority cannot be brought before the courts. Only occasional instances can be rectified by court action. This should not be surprising—it's the opposite side of the coin to FDA's position that it cannot enforce the statute on a case-by-case basis through the courts.

As a result, unless the Congress implements its role as legislator and carefully reviews FDA's exercise of its authority, there will be no genuine limita-

tions upon the agency's discretion. Until Congress examines basic FDA programs in greater detail than it now does, and imposes legislative restrictions upon inappropriate programs or procedures, the agency will continue to be free to legislate its own responsibilities.

Let me offer two situations to illustrate this point. The first relates to FDA's program for review of over-the-counter drugs, which Commissioner Schmidt discussed earlier today. The second concerns FDA's actions in connection with the statutorily mandated "opportunity for a hearing" in such situations as FDA's proposed withdrawal of a drug from the market or the agency's refusal to approve a new drug for marketing.

I. The OTC Drug Review

As the Commissioner has explained, the FDA determined that the only practical way to review the entire market of OTC products to determine their safety and efficacy was through a review by product classes, and not on a case-by-case basis. Consequently, the FDA began in 1972 to review all OTC products through a series of over-the-counter advisory committees, each dealing with a designated class of products.

I personally agree that the only practical way to review the entire OTC market was by some program along the lines adopted by FDA. Although many people, including a number of other lawyers in private practice, take the view that a case-by-case basis could be used, to my mind it is not nearly as effective or sensible as a class approach. Necessary though it was, however, the OTC Monograph system was not foreshadowed by any provision of the Food, Drug, and Cosmetic Act. In fact, it represented a fundamental departure from the case-by-case regulatory system embodied in the new-drug provisions enacted by Congress in 1938 and amended in 1962. The simple truth is that the OTC Review was manufactured out of whole cloth.

For example, the Food, Drug, and Cosmetic Act contains detailed provisions governing judicial review of agency actions respecting new drug applications. But it contains no provisions whatever for review of determinations made under the OTC Review. To resolve the problem, FDA was compelled to assert that review in a district court, under the general provisions of the Administrative Procedure Act, would be appropriate.

Such makeshift procedures, built from scratch by the agency and superimposed on the statutory framework created by Congress, might be justifiable as a short-term expedient to resolve a temporary problem. But the OTC Review is not an emergency measure. It is a fundamental new regulatory scheme that will, for thousands of drug products, entirely supplant the procedures specified by the Act. A regulatory system of its significance and long-term impact should have been the subject of Congressional deliberation. Its basic provisions should be embodied in the statute; they should not be controlled by regulations that FDA can amend or revoke at any time through informal rulemaking.

Recently, FDA has published proposed regulations that would significantly alter the procedures for marketing prescription drugs. Ultimately, the agency hopes to develop for prescription drugs a system of old-drug monographs similar to that being implemented for OTC drugs. It may well be that, upon reflection, Congress would approve these measures as FDA has proposed them. But, whether Congress would approve them or not, they should be submitted to the Legislative Branch as proposed amendments to the Food, Drug, and Cosmetic Act. They should not be "enacted" through the administrative fiat of FDA.

II. The FD&C Act's Provision for Opportunity for a Hearing in Connection with New Drug Regulation

I now turn to my second example—the FDA's treatment of the provisions of the FD&C Act providing for an "opportunity for a hearing" in connection with such matters as the agency's refusal to approve a new drug for marketing, or its proposed withdrawal of a drug from the market.

The FD&C Act—in such provisions as Sections 505 and 507—plainly contemplates that where factual issues are disputed, or clear differences of scientific judgment are involved, those differences must be resolved at a hearing. In recent practice, however, FDA has steadfastly sought to resolve all factual questions itself and to deny a hearing in cases where, by any proper standard, it is apparent that a hearing is required.

I recognize FDA's pragmatic interest in trying to eliminate hearings. It apparently feels that such hearings require too much time, and that its other work would be slowed by the diversion of its scarce manpower. In addition,

FDA is probably influenced by the fact that its hearings in past years have sometimes been unduly protracted and, indeed, have served as illustrations of the inefficiency of administrative hearings.

I read some days ago that Commissioner Schmidt had said in an interview that the FD&C Act should be amended to permit FDA to remove a drug from the market without a hearing. Unfortunately, FDA has for the past several years sought to administer the law as if Congress had already amended it to eliminate the hearing requirement. Such disregard of statutory provisions is not the proper answer to the agency's administrative difficulties. Two preferable solutions exist. First, FDA could seek to improve its hearing procedures and the manner in which hearings are conducted. Second, if the agency believes that the hearing requirement should be eliminated in some situations, it should seek appropriate legislation and justify its position to Congress.

As a practical matter, FDA's studied policy of circumventing the hearing requirements of the law probably cannot be reversed by the courts. The bulk of the agency's decisions are not reviewed by any court. In recent months, the agency has been criticized for its disregard of Congressionally-mandated procedures on a number of occasions, but judicial efforts to limit the agency's discretion and assure petitioners their statutory hearing rights have had little discernible effect on general FDA policy.

In *Weinberger* v. *Hynson, Wescott & Dunning*, 412 U.S. 609, 621 (1973), the Supreme Court upheld in principle the invocation of administrative summary judgment to deny a hearing on the withdrawal of approval for a new drug application when "it appears conclusively from the applicant's 'pleadings' that the application cannot succeed." In the two years since *Hynson*, FDA has expansively interpreted this portion of the Court's opinion. But it has ignored the broad significance of the Court's decision that the applicant in *Hynson* had, contrary to FDA's position, adduced enough evidence to warrant a hearing. In many subsequent cases, applicants have shown even more justification for hearings, but their requests have been denied.

Many such applicants have been in no position to seek judicial review. More important, routine resort to the courts should not be necessary to obtain a hearing guaranteed by law. FDA, no less than a private citizen, should adhere to the statute it administers without the need for direct judicial intervention.

In a number of recent cases where applicants have sought judicial review, the federal courts have ordered the agency to hold hearings and have voiced stern criticism of FDA's disregard for the procedural requirements of the Act.

Let me briefly cite a few examples. In *Hess & Clark, Division of Rhodia, Inc.* v. *FDA*, 495 F. 2d 975 (D.C. Cir. 1974), the Court of Appeals reviewed the procedures employed by FDA in withdrawing approval for an animal drug. Finding the case "unnecessarily confused" and the record "piecemeal," the Court said:

"What is at stake in this case is the integrity of the Commissioner's expertise in a broad sense, exercised, in the manner ordained by Congress, after genuine opportunity for hearing and consideration of controverted issues. We cannot allow important issues of law and public policy to be decided in a patchwork of legal theory that is sewn in a confusion inconsistent with responsible review." 495 F. 2d at 990.

After reviewing the submissions made by the petitioners in support of their requests for a hearing, the court concluded that substantial issues of fact existed. It said:

". . . The FDA must resolve these issues through the hearing mechanism. In the absence of the restraints available in the emergency situation, i.e., on a finding of imminent hazard to safety, the FDA cannot assert, as a matter of paternalistic sagacity, that it can dispose of these matters without opportunity for hearing." 495 F. 2d at 994.

On the same day, the court reached a similar conclusion in a related case. *Chemetron Corp.* v. *Department of HEW*, 495 F. 2d 995 (D.C. Cir. 1974).

In *Sterling Drug Inc.* v. *Weinberger*, 503 F. 2d 675 (2d Cir. 1974), the U.S. Court of Appeals for the Second Circuit reviewed the complex and lengthy history of the petitioner's efforts to obtain a hearing from FDA on the withdrawal of approval for its new drug application. FDA had twice issued orders withdrawing approval for the applicant's drug product and denying a hearing. In each case, the agency had reinstated approval for the product when the applicant sought judicial review. Setting aside the agency's third order withdrawing approval for the drug and denying a hearing, the Court of Appeals

said that it was "apparent that the FDA arbitrarily disregarded the requirements of the statute and its own regulations." 503 F. 2d at 682.

Mostly recently, in *Edison Pharmaceutical Co.* v. *FDA*, 513 F.2d 1063 (D.C. Cir. 1975), the Court of Appeals concluded that data submitted with the petitioner's new drug application were sufficient to warrant a full evidentiary hearing. The court went on to observe:

"We are re-enforced in our decision by the fact that between May 8, 1970, when FDA's summary judgment regulations went into effect, and April 4, 1973, when the government submitted its reply brief in *Hynson, the Commissioner had not granted a single request for a hearing on an NDA*. Even after the Supreme Court's decision in *Hynson*, which was cited by petitioner in its request for a hearing, the Commissioner still denied Edison's request for a hearing. In our eyes this failure to grant a hearing to any applicant casts doubt upon the good faith we would ordinarily impute without question to a decision of the Commissioner." 513 F.2d at 1072 (emphasis in original).

Conceivably, the extensive procedural regulations recently promulgated by FDA may presage a new respect for the procedural requirements imposed by Congress. In the absence of some Congressional prodding, however, I am not confident that this will be the case, for the new regulations reflect the old policy. They seek in many cases to supplant the hearings provided for by Congress with new procedures, never the subject of legislative deliberation, that will substantially diminish the rights of regulated persons. Similarly, the regulations appear to place additional requirements on obtaining a hearing that find no place in the statute.

As a result, I must return to my basic point—if FDA wants to change the procedures set forth in the statute, it should do so by proposing legislation to Congress, and not by disregarding Congress' instructions.

It seems to me that it would be well if we saw more hearings at FDA and at least somewhat fewer FDA hearings in Congress. In my own personal view, at least some of the extensive Congressional hearings in which FDA has been almost constantly engaged in recent years do not justify the extreme demands in preparation and attendance that they place upon senior FDA officials. I frequently wonder how necessary and important decisions can be made on a day-to-day basis at FDA when its principal officials are running from one Congressional hearing room to another to review again and again, not general policy matters, but particular factual situations of limited importance and interest. By contrast, an occasional review—perhaps on an annual basis—by a committee such as this of basic questions of FDA policy and the FDA record in dealing with the legislation enacted by Congress would be fruitful and of continuing value.

Senator Abourezk. I think we shall finish this afternoon.

Thank you very much. We will reconvene at 2:30 today.

[Whereupon, at 12:25 p.m., the subcommittee recessed until 2:30 p.m. the same day.]

AFTERNOON SESSION

Senator Abourezk. Mr. Temko, I think you had finished your statement.

Does anyone else have a statement?

TESTIMONY OF RAYMOND D. McMURRAY, McMURRAY AND PENDERGAST

Mr. McMurray. Mr. Chairman, I am Raymond D. McMurray, a member of the bar and a partner in the law firm of McMurray & Pendergast, with offices here in Washington, D.C.

I am pleased, Mr. Chairman, to have this opportunity to appear before the subcommittee—together with the other members of the panel—to offer my comments, and to answer the subcommittee's questions, in pursuit of its congressional oversight of the functioning of the Food and Drug Administration. I will try to skip over some parts

of my prepared statement, since I understand, Mr. Chairman, that it will be printed in the record of this hearing.

Let me state that I have spent 21 of my 25 years in practice dealing with problems arising under the Federal Food, Drug, and Cosmetic Act, and as a consequence, dealing with the Food and Drug Administration. For 10 years, I was general counsel to two pharmaceutical manufacturers: one, in Cincinnati, Ohio, from 1954 to 1958, the other in Nutley, N.J., from 1958 to 1964. When I returned to private practice 11 years ago, it was logical and inevitable that I should represent clients regulated by the FDA. Presently our firm's practice, though not entirely so limited, is nevertheless heavily in the area of food, drugs, cosmetics, and devices. My practice thus gives me continuing contact with the Food and Drug Administration.

I have seen the agency grow over the last 21 years from a relatively small bureau, which emphasized a regulatory role, to a large, multidivision bureaucracy which, because of its size, tends to be somewhat sluggish and, because of its own sense of direction, tends to emphasize a greater scientific role than it does its enforcement mission. I do not wish to engage in any petty vituperation here today, and therefore I hope to offer the subcommittee some constructive comments. I would like to preface that to say that I believe that the performance of any agency—and I am speaking as an individual and not for anyone else—but it seems that the performance of any agency is in the last analysis the performance of the particular person that you are dealing with at the time. And I have had my share of excellence on the other side as well as, I am sorry to say, my share of frustrations with those with whom I have dealings.

But in the large measure, I think the Food and Drug Administration has in the overall tried, rightly or wrongly in application, to carry out its mission.

This morning, the Commissioner, to make a point, went back as far as 1938. I think that the basic act, which is the 1938 act—I think the source of the changes made in FDA, and perhaps as well the source of the more substantial areas of confrontation and dispute, can be traced to the 1962 drug amendment. Prior to those amendments as to drugs, the new drug applications were required to contain proof only as to safety of the particular product, and not specifically as to efficacy.

The 1962 legislation required that following its effective date in October of that year, the new drug applications must prove not only that the drug product was safe, but also effective—and not only effective, but effective for its indications.

In addition, all drugs that had been subject to the new drug applications between 1938 and 1962 were to be reviewed for similar proof of efficacy under the newly established standard.

Now, you can readily recognize, Mr. Chairman, that faced with this herculean task the agency had to expand rapidly and extensively. In doing so, and in applying its new statutory standards, they adopted and pursued a scientific rather than a regulatory course of administration. Whether or not this is indeed the mission which the Congress intended the Food and Drug Administration to undertake in enacting and amending the Food, Drug, and Cosmetic Act, the fact remains that the greater portion of the discord as I see it between the

agency and the regulated companies involved differences of opinion on the scientific, or even specifically on the medical level. And this does not only apply just to drugs, it applies also to food and cosmetics and devices. The personification of this trend, I point out, is the fact that the last four Food and Drug Commissioners have been doctors of medicine. Now, you heard Commissioner Schmidt this morning speak of all of the various laws that had to be administered by this agency. A doctor of medicine is not necessarily by his training a man who can take charge of all of these areas. If a person is a doctor of medicine, along with a capable administrative background which I am happy to say the present Commissioner does have, then that is fine. But I think that by having doctors of medicine head of the Agency you tend to have a drug oriented administration, and an administration which tends to interfere quite regularly with the practice of medicine.

Furthermore, this is not merely a regulatory act, it is criminal, as we have been reminded quite sharply in the recent *Park* decision on the food side. It is a criminal statute and must be administered with that in mind. So its administration must be precisely within the limit of the enabling law, and the agency rules must be clear and unambiguous. Its decisions and pronouncements must be so clear that the regulated independent industries, and indeed the individuals involved, are fully informed of the attitudes of the FDA.

I do not agree with Ms. Greenberger who spoke today that in fact the pharmaceutical industry or the regulated industry in any of its parts and the consumer are pitted against each other. I believe in all my years of practice that none of my clients have ever wanted to circumvent the law, though sometimes through inadvertance or some other reason they came outside the law. But I do not believe the regulated industries do other than perform a useful public service. And there is no antagonism—and I am a consumer, though I represent the industry at the same time.

Senator Abourezk. May I interrupt you for a minute.

How could you characterize the relationship, if it is not an adversary relationship, between the consumer and the industry?

Mr. McMurray. I think it is a parallel relationship.

Senator Abourezk. You mean they work together?

Mr. McMurray. I think they should.

Senator Abourezk. Do they?

Mr. McMurray. I think they do as much as they possibly can. Indeed, I do not believe that the regulated industries are consciously or in any way attempting to fool or otherwise engage the consumers in some kind of an adversary situation.

Senator Abourezk. Maybe they are not attempting to do so, but what is the results? What happens in actual practice?

Mr. McMurray. I think the Food and Drug Administration, in carrying out its mandates, is performing the function of providing the kind of oversight of the industry that the consumer wants to superimpose.

Senator Abourezk. My question is, no matter what the industry might intend, what is the result of what they do? Does it then become an adversary relationship between the industry and the consumer?

Mr. McMurray. I do not believe so.

Senator Abourezk. You do not believe so. But you said a minute ago that you believed there was some adversary relationship.

Mr. McMURRAY. I think Ms. Greenberger attempts to set one up. I never have had the feeling from being in the industry that the consumers was an adversary. The consumer after all is to be served by any industry that sells products. And there cannot be an adversary relationship between an industry and the people that are being served.

Senator ABOUREZK. I would take issue with that particular concept. I think it is an adversary relationship between any industry and the consumer.

Mr. McMURRAY. That is your privilege, Senator.

May I proceed?

Senator ABOUREZK. Please.

Mr. McMURRAY. To be constructive, then, and to offer some thoughts, as I have said, the first constructive thought I would like to offer is that the FDA should be headed by a Commissioner with proven administrative abilities. Whether he is a medical doctor or not should be one consideration, but not the overriding consideration.

Second, I believe that the emphasis of the agency should return to enforcement, for the reasons that I have already stated. The detour to scientific emphasis, and sometimes into medical judgment, can sometimes be explained, but not always justified.

There have been recent disputes where the subject has not been the safety or the efficacy of the product, or where the FDA suggests that new drugs be used, or that the physician limit drugs only to certain patients, or that the FDA considers the current use of certain drugs appropriate for prescriptions. These tend to be beyond the mandate of the Congress, I believe.

Now, third, let me get into areas that were spoken of this morning. I cite one or two examples which it seems to me suggest potential for correction in the area of due process, which is what we were asked to comment on primarily. There are three areas that I would like to talk about: Delay, unannounced regulatory decisions, and hearings. Nothing is more fundamental in our system of jurisprudence than the opportunity to be heard, the right to be informed of one's obligations or privileges under the law, and the right to a speedy determination of any petition or controversy.

As far as delay is concerned, all of us who practice before FDA can cite numbers of instances where either statutory or regulatory time limits have been disregarded by the agency to the actual or potential harm not only of the regulated firms but the public as well. FDA is very often quite cavalier in failing to meet time deadlines imposed upon it by its own regulations, and indeed of the act itself.

In the area of unannounced regulatory decisions, it is important that the regulated industries know the rules under which they are expected to operate. Consequently, unpublicized administrative decisions result either in favoritism among regulated companies, or hidden dangers for the uninformed. Even with the Freedom of Information Act, there are still areas in which the regulated industry is left in the dark. One recent example involves a regulatory decision which, in my opinion, reversed long-standing law and practice at the agency but was not communicated generally. In this case, the holder of a new drug application complained that a competitor was marketing an identical drug product without first having obtained an approved abbreviated new drug application. The agency abruptly announced that the competitor would not be proceeded against as long as it had filed an NDA even

though the application had not yet been approved. This agency policy is, in my judgment, not only contrary to the law, and to the governing regulations, but the manner in which the decision came to light was, at best, embarrassing to the FDA. Certainly it left those of us at the bar, who had previously counseled clients to wait for NDA approvals, as required by statute and regulation, before going to market.

Now, as to, I think, an example of the kind of mischief which might occur under the newly promulgated FDA procedural regulations, consider the following: The law (section 505(c)(2)) in providing for a notice of an opportunity for a hearing, after the FDA has denied approval of an NDA, states that if the applicant elects to accept such opportunity by written request within 30 days, such hearing shall commence not more than 90 days after the expiration of such 20 days unless the Secretary and the applicant otherwise agree. The hearing thereafter must be conducted on an expedited basis.

Section 2.118 of the new procedural regulations, it seems to me, flies straight in the face of the statute. It provides (in subparagraph (c)) that a formal evidentiary public hearing shall be deemed to commence as of the date of publication of the notice of hearing in the Federal Register. Thus, by the mere act of publishing a deemed commencement date, the FDA has in effect deprived the applicant of his right not to grant FDA an extension of time beyond the statutory 90 days; and, perhaps even more of a denial of due process, presumes to meet the statutory requirement of a commencement of a hearing which, under the very regulation cannot really get underway unless and until a presiding officer has been appointed and other housekeeping matters are taken care of. The designation of a presiding officer is left to the sole discretion of the Commissioner without any time limit stated in which he is to act. And as Ms. Greenberger said this morning, with no time limits on the Food and Drug Administration anywhere in these regulations, not only the consumer but the regulated industry is affected.

In other words, once going through the formality of publishing a notice of hearing, literally years could go by without any actual presentation of evidence. Inherent in this kind of regulation are the seeds of denial of due process. The next couple of pages I merely summarize because they deal, Mr. Chairman, with the exchange which Mr. Tobias had their morning with Mr. Merrill concerning the fact of almost presenting your case and having to win it before you are granted a full evidentiary hearing. Mr. Merrill, you will recall, relied on the four Supreme Court cases which were argued and decision rendered in 1973. In my judgment these cases are not warrant for the FDA to lump all hearings into the category of section 505, which is the new drug section of the law, into one basket. Section 505 of the law does indeed talk in terms of opportunity for a hearing. And there is some justification the Supreme Court has said the procedure is all right. Section 701(e) rulemaking hearings, on the other hand, are quite specific, and do not qualify the right to a hearing, they say there is a right to a hearing, not the right to an opportunity for a hearing.

And it is true that in other agencies hearings are held for the purpose of putting the agency to its proof, if it has made a decision. And I think that that is one area these regulations could be looked at again and possibly revised to reflect what I see is a dichotomy.

Finally, Mr. Chairman, these hearings in my judgment come at an important moment in the life of the Food and Drug Administration. We are about to have a new Secretary of Health, Education, and Welfare. And we have a new general counsel of FDA and the Agency has just published these new regulations concerning the administration, and I assume have published similar regulations concerning enforcement.

The opportunity to comment and have the Agency clarify its meaning and to have this subcommittee at the threshold of these circumstances review the Food and Drug Administration procedural operations is most fortunate, in my judgment. In addition, it reassuring, I think, to have the new General Counsel suggest, as he has on occasion, that he may prefer to adopt a different regulatory approach than that of his predecessors. There is a new day dawning, and your investigation is certainly very timely.

And I thank you for hearing me, Mr. Chairman.

[The prepared statement of Mr. McMurray follows:]

PREPARED STATEMENT OF RAYMOND D. MCMURRAY, ESQ.

Mr. Chairman, I am Raymond D. McMurray, a member of the bar and a partner in the law firm of McMurray and Pendergast, with offices here in Washington, D.C.

I am pleased, Mr. Chairman, to have this opportunity to appear before the Subcommittee—together with the other members of the panel—to offer my comments, and to answer the Subcommittee's questions, in pursuit of its Congressional oversight of the functioning of the Food and Drug Administration.

In your letter of invitation, you referred to me as "an attorney who often deals with the Food and Drug Administration on behalf of regulated parties". In support of this observation, Mr. Chairman, let me state that I have spent 21 of my nearly 25 years in practice dealing with problems arising under the Federal Food, Drug and Cosmetic Act, and as a consequence, dealing with the Food and Drug Administration. For 10 years I was General Counsel to two pharmaceutical manufacturers: one, in Cincinnati, Ohio, from 1954 to 1958, the other in Nutley, New Jersey, from 1958 to 1964. When I returned to private practice 11 years ago, it was logical and inevitable that I should represent clients regulated by the FDA. Presently our firm's practice, though not entirely so limited, is nevertheless heavily in the area of food, drugs, cosmetics and devices. My practice thus gives me continuing contact with the Food and Drug Administration.

I have seen the Agency grow over the last 21 years from a relatively small bureau, which emphasized a regulatory role, to a large, multi-division bureaucracy which, because of its size, tends to be somewhat sluggish and, because of its own sense of direction tends to emphasize a greater scientific role than it does its enforcement mission.

Mr. Chairman, let me preface my remarks by disavowing any purpose to engage here today in petty vituperation. I am confident we all would agree that every regulatory agency has its faults, that both the public (particularly consumer-represented) and the relevant regulated industries could catalog a list of criticisms of its administration—some significant, some minor. Equally one could catalog a list of tributes to its functioning. Those of us who deal with the Federal bureaucracy have come to accept that there are frustrations built into the system.

Performance within an agency is, in the final analysis, only as good as the person in immediate charge of one's particular matter; and I must say that I have met my share of excellence within the Food and Drug Administration, as well, I am sorry to say, as my share of varying degrees of a lack thereof.

In large measure, therefore, one's evaluation of the performance of any agency of government is more or less subjective, depending upon our individual experiences with that particular regulatory agency.

So it is with the Food and Drug Administration; it is no exception.

But, I take it the objective of this inquiry by the Subcommittee is to determine whether, *in the overall*, the Food and Drug Administration is properly carrying

out, within the limits set by the Congress, its statutory mission and whether, in so doing, it is proceeding fairly and rationally, consistent with our underlying concept of due process.

Mr. Chairman, I believe the source of the greatest change in the FDA and, perhaps as well, the source of the more substantial areas of confrontation and dispute, can be traced to the 1962 Drug Amendments. Prior to those amendments, as to drugs, "new drug" applications were required to contain proof only as to the *safety* of the product and not *specifically* as to its efficacy. This is not to say that efficacy was not a factor in evaluating a drug product in the years between 1938 and 1962, since *safety* is always a relative matter. Indeed, then Commissioner Larrick so testified with respect to the pending legislation which thereafter was enacted as the 1962 Drug Amendments.

The 1962 legislation required that following its effective date (October 10) "new drug" applications must prove not only that the drug product is safe, but also—and this by *substantial evidence* (which is specifically defined in the Act and so are words of art)—that the product is effective for its indications. In addition, all drugs which had been the subject of "new drug" applications between 1938 and 1962 were to be reviewed for similar proof of efficacy under the newly-established standard.

You can readily recognize, Mr. Chairman, that, faced with this Herculean task, the Agency had to expand rapidly and extensively. In so doing, and in applying this new statutory standard, it adopted and pursued a "scientific", rather than a "regulatory" course of administration. Whether or not this is indeed the mission which the Congress intended the Food and Drug Administration to undertake in enacting and amending the Food, Drug and Cosmetic Act, the fact remains that the greater portion of the discord between the Agency and the regulated companies involves differences of opinion on the scientific—even, specifically, the medical—level. And this is true not only for drugs but also for foods, cosmetics and devices.

The personification of this trend, one might point out, is the fact that the last four Food and Drug Commissioners have been doctors of medicine; and it would appear that this is likely to continue. Although I do not believe that because a good administrator happens to be a doctor of medicine, this fact should disqualify him as Commissioner, it nevertheless seems to me, in view of the broad enforcement function of the FDA, that the emphasis should be on administrative experience rather than medicine.

Let us not lose sight of the fact that the Federal Food, Drug and Cosmetic Act is a regulatory statute; its mission is not, as I have said, to oversee the practice of medicine. The comment by Commissioner Schmidt, in his recent correspondence on the cyclamates, suggests to me that he, at least, so understands. In stating that the Agency's responsibility was to determine the safety and functionality of these compounds, he observed that it had to be left to the practicing physician to determine their benefit and need.

Moreover, Mr. Chairman, this Act is not merely regulatory in nature but, as we have so sharply been reminded by the recent Supreme Court decision in the *Park* case, it is a *criminal* statute, and as such must be administered with that in mind. Consequently, not only must its administration be precisely within the limits of the enabling law, but the Agency's rules and regulations must also be clear and unambiguous.

Its decisions and pronouncements must be equally clear, so that the regulated industries—and the individuals involved—are fully informed of the attitudes of the FDA. Only then can it be said that "fair warning" has been given those who may find themselves faced with criminal charges; only then, indeed, can compliance be assured. Unfortunately, Mr. Chairman, this has not always been the case.

In all my years in practice, both within the pharmaceutical industry and as a private practitioner, I have never once had to face a situation where my client did not wish to comply with the requirements of the law. I have had clients who were unaware of these requirements, and others who were unable to comply, perhaps because of economics or physical limitations of plant. But no one has ever indicated anything less than a firm desire to abide by the law. Indeed, many have elected to comply with the Agency's interpretation of the law, despite a firm belief that the FDA was overstepping its authority; choosing compliance as the less painful and expensive expedient than suffering prolonged litigation or other regulatory proceedings.

Be that as it may, Mr. Chairman, I would like to be constructive here today and to suggest several positive things which, in my judgment, could help both the FDA and the public.

First, I believe the FDA should be headed by a Commissioner with proven administrative abilities. If he happens to be an M.D., and the present commissioner is an M.D. with proven administrative abilities, that medical background should be only one factor, but not a major one. A good administrator is worth more, in my judgment, in such a position than someone with a series of advanced degrees but no administrative training and experience. Moreover, subordinating medical training to administrative experience may serve to de-emphasize the what-is-sound-medical-practice attitude which appears now to prevail.

Secondly, I believe the emphasis of the Agency should return to enforcement. For the reasons I have already stated, the Agency's "detour" to scientific emphasis, and, in that connection, to judgments on medical practice, can be explained but not justified. In the last few years the FDA appears to have operated on the principle, as described by its former General Counsel, that if there is nothing in the law to prohibit a particular activity than such activity will be undertaken. For an agency with delegated authority, this sounds like heresy.

The exercise of such "medical practice judgments" are responsible for situations like the recent ones where the dispute is not as to safety or efficacy of the product but where the FDA suggests that newer drugs be used [cephalosporin] or that the physician limit the drugs to only certain of his patients [oral hypoglycemics], or that the FDA considers the current use of certain drugs as inappropriate for prescribing by physicians [antibiotics—clindamycin and lincomycin].

Thirdly, let me cite one or two examples which, it seems to me, suggest potentials for correction in the area of due process. I would comment on three: (a) Delay; (b) Unannounced regulatory decisions. and (c) Hearings.

Nothing is more fundamental in our system of jurisprudence than the opportunity to be heard, the right to be informed of one's obligations or privileges under the law, and the right to a speedy determination of any petition or controversy.

Delay

All of us who practice before the FDA can cite numbers of instances where either statutory or regulatory time limits have been disregarded by the Agency to the actual or potential harm not only of the regulated firms but the public as well. FDA is very often quite cavalier in failing to meet time deadlines imposed upon it by its own regulations (as well as the Act itself)—and this, often, without so much as a "by your leave".

Unannounced regulatory decisions

As I have said it is important that the regulated industries know the rules under which they are expected to operate. Consequently, unpublicized administrative decisions result either in favoritism among regulated companies, or hidden dangers for the uninformed. Thus, despite the publication of an extensive set of regulations, in compliance with the Freedom of Information Act, there are still areas in which the regulated industry is left in the dark. One recent example involves a regulatory decision which, in my opinion, reversed long-standing law and practice at the Agency but was not communicated generally.

In this case, the holder of a "new drug" application complained that a competitor was marketing an identical drug product without first having obtained an *approved* abbreviated "new drug" application. The Agency abruptly announced that the competitor would not be proceeded against as long as it had *filed* an ANDA even though the application had not yet been approved. This agency policy is, in my judgment, not only contrary to the law, and to the governing regulations, but the manner in which the decision came to light was, at best, embarrassing to the FDA. Certainly it left those of us at the Bar, who had previously counseled clients to wait for NDA approvals, as required by statute and regulation, before going to market, with considerable explaining to do.

Hearings

As an example of the kind of mischief which might occur under the newly promulgated FDA procedural regulations, consider the following: The law (Sec-

tion 505(c)(2)), in providing for a notice of an opportunity for a hearing, after the FDA has denied approval of an NDA, states that if the applicant elects to accept such opportunity by written request within 30 days, *"such hearing shall commence* not more than 90 days after the expiration of such 30 days *unless the Secretary and the applicant otherwise agree."* (Emphasis mine). The hearing thereafter must be conducted on an "expedited basis."

Section 2.118 of the new procedural regulations, it seems to me, flies straight in the face of the statute. It provides (in subparagraph (c)) that a formal evidentiary public hearing shall be "deemed to commence" as of the date of publication of the notice of hearing in the Federal Register.

Thus, by the mere act of publishing a "deemed" commencement date, the FDA has in effect deprived the applicant of his right *not* to grant FDA an extension of time beyond the statutory 90 days; and, perhaps even more of a denial of due process, presumes to meet the statutory requirement of a *commencement* of a hearing which, under the very regulation cannot really get under way unless and until a presiding officer has been appointed and other housekeeping matters are taken care of. The deregulation of a presiding officer is left to the sole discretion of the Commissioner without any time limit stated in which he is to act. In other words, once going through the formality of publishing a notice of hearing, literally years could go by without any actual presentation of evidence. Inherent in this kind of regulation are the seeds of denial of due process.

Furthermore, it has become quite apparent to those of us practicing before the Agency that there is a definite anti-hearing bias. This reluctance to have evidentiary matters aired in public on an adversary basis culminated in four Supreme Court decisions in June of 1973. In large measure the Court approved the Agency practice of granting hearings only on a showing by the applicant of substantial evidence and finding by the Commissioner that there was an issue of fact to be tried. In its new procedural regulations the Agency relies on these cases to lump together *all* requests for hearings when, in fact, the Supreme Court decisions dealt with hearings under Section 505 of the Act and not any other section.

The significance and the difference is that it is now established that hearings involving "new drug" applications can only be had when the Commissioner offers an applicant "an opportunity for hearing" and decides that there is an issue of fact to be tried. Other areas of the law, relating to food standards, special dietary foods, and food additives, are generally subject, with certain modifications, to Section 701(e) of the Act which is quite specific in granting a hearing without any qualification. In equating both types of proceedings, and treating both as cases in which a person has only a right to an *opportunity* for a hearing, the regulation ignores the clear language of the statute and the considerable legislative history in favor of hearings. The regulation also subjects the applicant to certain requirements concerning the form and content of objections and requests for a hearing [Section 2.112] and to the restriction that a request for a formal evidentiary public hearing shall be granted only if the person requesting such hearing has met *all* of six specified conditions. [Section 2.113]. I believe that such evidentiary burdens and restrictive criteria for granting hearings are contrary to the statute, under which FDA is required to grant hearings.

First, with respect to Section 701(e) rulemaking hearings, the statute, on its face, provides for a hearing to adversely affected parties, *not* merely an "opportunity for hearing." Thus, whatever feelings of comfort FDA may derive from judicial decisions interpreting the section of the Act providing for "opportunity for hearing" cannot properly be applied to Section 701(e) proceedings.

Second, with respect to the form of objections, Section 701(e), on its face, contains no basis for FDA's attempt in the regulations to require a "detailed and specific" showing of evidence in support of objections [Section 2.112]. Rather, the statute requires only that the adversely affected person "[specify] with particularity the provisions of the order deemed objectionable, [and state] the grounds therefore, [and request] a public hearing upon such objections."

In practice, these requirements have been construed to permit objections which raised no independent evidentiary assertions, but simply sought to put the Agency to its proof with respect to proposed regulations, or particular parts thereof. Moreover, it has never previously been suggested that the statute required the kind of detailed advance evidentiary presentation called for by new regulations [Section 2.112]. Prior practice under Section 701(e), I believe, accords with the legislative history of that statute.

When the FDA overreaches in its statutory authority, as, for another example, in mandating cosmetic ingredient labeling, or so-called common or usual names

for certain prepared foods, it is no light task to overcome its determination. Court review, of course, is available. But given both its cost and its time consumption, it is no answer—surely not for the individual entrepreneur, not even for the large corporation.

The authority vested in the FDA by the Congress—an authority made far more draconian by the *Park* decision, to which I have already referred, and the breadth of the opinions in the "Drug Cases" of 1973—emphasizes the substantial risks to which the regulated industries are exposed. And again reminding you that the Food, Drug and Cosmetic Act is a criminal statute, it is imperative, as I have said, that the Agency's rules, regulations and procedures be crystal clear, unambiguous and fair, so that "fair warning" be given to those who may be called upon, in a criminal prosecution, to vindicate their actions.

These hearings come as an important moment in the life of the Food and Drug Administration. We are about to have a new Secretary of Health, Education and Welfare. We have a new General Counsel to the FDA, the Agency has just published new procedural regulations concerned with administration, and it will soon publish similar regulations concerned with enforcement. Although these are published as "final", comments have been solicited. The opportunity to comment, to have the Agency clarify its meaning, and to have this Subcommittee, at the threshold of these circumstances, review the Food and Drug Administration's procedural operations, is most fortunate. In addition it is reassuring to have the new General Counsel suggest that he may prefer to adopt a different regulatory approach from that of his predecessor.

Perhaps now we will return to the time-honored principles of administrative law. Thank you, Mr. Chairman.

Senator ABOUREZK. Before we go on with the next statement, I want to say that I am asking the staff of this subcommittee to get together with all four of you and Ms. Greenberger to try and distill your recommendations so that we might derive some remedial legislation on these areas of concern.

I think the points that Mr. Temko raised this morning about the FDA going beyond its authority, I agree with. I think they ought to stay within their statutory authority or ask for new legislation. And I think in that regard if we derive anything from these hearings, it will be very beneficial.

TESTIMONY OF JANE LANG McGREW, STEPTOE & JOHNSON

Ms. MCGREW. Senator, my name is Jane McGrew. I am an attorney with the Washington law firm of Steptoe & Johnson.

I want to thank you first for inviting me to testify. I am flattered to be in such distinguished company. It seems to me today that the theme of most remarks has been that of change: change in the industry, change in the consumer, and as a result, change in the law as administered by the FDA. This theme of change I think is particularly significant and appropriate for this subcommittee. It is also at the subject of my statement.

The agency which is entrusted with the regulation of the dynamic and sophisticated drug industry must be flexible and innovative. It must be prepared to take the initiative to deal with circumstances which have changed substantially since 1938. FDA has accepted this role in devising procedures to handle the huge volume of NDA's and drug reviews, to adapt to the increased demand for public participation, to acquire access to technical expertise, to respond to complaints about delay, and to accommodate industry representation. In so doing, it legislates and adjudicates in ways never anticipated by the Congress, as illustrated by its new procedural regulations, which are the basis of my discussion this afternoon.

The agency's willingness to exercise initiative and to adapt to change are apparent in these regulations. They eliminate arbitrary and archaic standing rules which other agencies of Government persist in; they state that FDA will be impressed by the substance of comments rather than the number, which should satisfy at least one of Ms. Greenberger's concerns expressed this morning. They provide for nonvoting industry representation on advisory committees, and they evenhandedly demand that citizens and public interest groups, no less than industry, show that a request for agency action is premised on fact, not speculation.

In taking the initiative in many of these matters, the FDA has avowedly gone beyond the express authority of the Food, Drug, and Cosmetic Act. This fact does not trouble me, however. The concept of separation of powers can debilitate agency regulation, if allowed to do so, as the Supreme Court has recognized. The importance of the concept lies, after all, in the fact that it serves the operative principle of checks and balances which is essential to democracy. Thus, as long as the Congress, the executive, and the judiciary are prepared to exercise their powers to check agency initiative, we should not allow ourselves to become too distracted by the threat to constitutional doctrine posed by the FDA.

I am, however, very concerned when FDA becomes so enamored of innovation that it flouts the laws which govern its conduct. The new procedural regulations abound with examples of FDA's disregard for the Administrative Procedure Act. To begin with, the promulgation of 100 pages of regulations and preambles as final, rather than proposed, rules, is wholly improper and unjustified. It is as if the Supreme Court promulgated an entire new body of Federal rules of civil procedure without giving Congress the chance to exercise its veto power. While many of these regulations deal with internal administrative matters or statements of position which FDA will adopt in courts, others affect substantive rights and procedures which warrent careful thought and participation of the public and the industry.

Another troubling aspect of the regulations is the formal creation of that special category of rules called guidelines, which will not be subject to the usual APA rulemaking procedures. The justification for the distinction is that the guidelines will not establish legal requirements; they may, however, be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards for compliance with the law. Anyone familiar with the recent Supreme Court decision in *Moody* v. *Albemarle Paper Co.* which deferred 100 percent to an agency's guidelines promulgated without opportunity to comment, should be very concerned about FDA's blithe evasion of the APA procedures for rulemaking.

The procedural regulations also cast aside the right to cross-examination in adjudicatory hearings. The party who seeks to exercise that right must make and justify a request to do so. To be sure, the right of cross-examination can be and has been abused. But it is the responsibility of a judge or hearing examiner to control any excesses. It is not the responsibility of the FDA to revoke provisions of the APA which it finds troublesome. Nor does it become the agency to tamper so freely with the rules of due process.

The Federal Advisory Committee Act (FACA) is also in some difficulty under the new FDA regulations. First, an advisory committee, we learn, is not limited to the giving of advice at the FDA. Despite the provision of the FACA which Mr. Tobias quoted this morning that "advisory committees shall be utilized solely for advisory functions," the FDA advisory committee can also serve as a public board of inquiry for the purpose of adjudication and decisionmaking. As your earlier questions to Dr. Schmidt suggested this morning, there is sufficient confusion about the role of advisory committees at the FDA in the minds of the members, the agency personnel, and in some cases, the Congress. Control of these committees under the act will inevitably be diluted and their stature clouded if they become multipurpose entities.

Another problem arises out of the Commissioner's determination, now reenforced by a regulation, to protect the transcripts of closed advisory committee deliberations from disclosure. While the Supreme Court has affirmed the privacy of intraagency deliberations, no such right has been extended by statute to the advisory committee, unless either agency memorandums or industry trade secrets are part of the discussions. Moreover, even were the freedom established to close committee deliberative sessions which do not concern protected subjects, there would still be no legal basis for maintaining the secrecy of the process after the committee's advice had been acted upon by the Commission. As Dr. Crout, Director of the Bureau of Drugs, testified last year, access to an advisory committee transcript is important "because it is true that without that, you may fail to capture important information." Why, then, should those transcripts, edited to delete protected material, remain permanently within the exclusive province of the agency?

In contrast to the firm position taken on the secrecy of transcripts or advisory committee deliberations, the FDA regulations are schizophrenic with respect to the confidentiality of safety and effectiveness data. As the FDA recognizes, these data are protected as trade secrets under the Food, Drug, and Cosmetic Act. Indeed, Mr. Merrill, I believe, stated this morning that he feels that the agency is "not at liberty" to make safety and effectiveness data public. Nevertheless, when these data are involved in a hearing, they will hereafter be on public display and may be examined but not recorded or transcribed verbatim. I recognize the difficulty which the FDA has faced in reconciling its objective of effective public participation with the statutory prohibition against revealing (not just copying) trade secrets. But a statutory prohibition cannot be discarded by agency fiat. The balancing of interests, particularly of this magnitude, lies at the heart of the legislative function. FDA's discretion in this balancing act has been explicitly limited by statute. If it is time for a change, the Congress—not the Commissioner—should see to it. The FDA, like any other agency, should not enjoy the exercise of unencumbered discretion by default of any other branch of Government.

Despite these criticisms, however, I consider the new procedural regulations a remarkable undertaking by the FDA to let everyone know how things work within the agency. This is in the interest of the public of which, we should remember, the drug industry is part.

[The prepared statement of Ms. Jane McGrew follows:]

PREPARED STATEMENT OF MS. JANE MCGREW

The agency which is entrusted with the regulation of the dynamic and sophisticated drug industry must be flexible and innovative. It must be prepared to take the initiative to deal with circumstances which have changed substantially since 1938. FDA has accepted this role in devising procedures to handle the huge volume of NDAs and drug reviews, to adapt to the increased demand for public participation, to acquire access to technical expertise, to respond to complaints about delay and to accommodate industry representation. In so doing, it legislates and adjudicates in ways never anticipated by the Congress, as illustrated by its new procedural regulations.

The agency's willingness to exercise initiative and to adapt to change are apparent in these regulations. They eliminate arbitrary and archaic standing rules[1] which other agencies of government persist in; they state that FDA will be impressed by the substance of comments rather than the number;[2] they provide for nonvoting industry representation on advisory committees;[3] and they even-handedly demand that citizens and public interest groups, no less than industry, show that a request for agency action is premised on fact, not speculation.[4]

In taking the initiative in these matters, the FDA has avowedly gone beyond the express authority of the Food, Drug and Cosmetic Act.[5] This fact does not trouble me, however. The concept of separation of powers can debilitate agency regulation, if allowed to do so, as the Supreme Court has recognized.[6] The importance of the concept lies, after all, in the fact that it serves the operative principle of checks and balances which is essential to democracy. Thus, as long as the Congress, the Executive and the judiciary are prepared to exercise their powers to check agency initiative, we should not allow ourselves to become too distracted by the threat to constitutional doctrine posed by the FDA.

I am, however, *very* concerned when FDA becomes so enamoured of innovation that it flouts the laws which govern its conduct. The new procedural regulations abound with examples of FDA's disregard for the Administrative Procedure Act. To begin with, the promulgation of 100 pages of regulations and preambles as final, rather than proposed rules, is wholly improper and unjustified.[7] It's as if the Supreme Court promulgated an entire new body of federal rules of civil procedure without giving Congress the chance to exercise its veto power.

Another troubling aspect of the regulations is the formal creation of that special category of rules called guidelines, which will not be subject to the usual APA rule-making procedures.[8] The justification for the distinction is that the guidelines will not establish legal requirements; they may, however, "be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards"[9] for compliance with the law. Anyone familiar with the recent Supreme Court decision[10] which deferred 100% to an agency's guidelines promulgated without opportunity to comment should be very concerned about FDA's blithe evasion of the APA procedures for rule making.

The procedural regulations also cast aside the right to cross-examination in adjudicatory hearings.[11] The party who seeks to exercise that right must make and justify a request to do so.[12] To be sure, the right of cross-examination can be and has been abused. But it is the responsibility of a judge or hearing examiner to control any excesses. It is not the responsibility of the FDA to revoke provisions of the APA which it finds troublesome. Nor does it become the agency to tamper so freely with the rules of due process.

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[1] 21 C.F.R. §§ 2.11(d)(1)(ii) and 2.23.
[2] 21 C.F.R. § 2.10(c)(1).
[3] 21 C.F.R. § 2.232.
[4] *See, e.g.*, 21 C.F.R. §§ 2.7(b) and 2.8(b).
[5] *See, e.g.*, 40 F.R. 22950 (May 27, 1975).
[6] *See* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973).
[7] APA, § 553(b); FDC Act, 21 U.S.C. § 371(e).
[8] 21 C.F.R. § 2.20(b).
[9] 21 C.F.R. § 2.20(b)(8).
[10] Moody v. Albemarle Paper Co., —— U.S. —— 1975 (EEOC testing "guidelines" upheld).
[11] 21 C.F.R. § 2.154(b) and (c). *See* APA, § 556.(d).
[12] There are five standards of justification, including "whether a dispute concerns facts in contrast to the inferences and conclusions to be drawn from the facts." 21 C.F.R. § 2.154(c)(4).

The Federal Advisory Committee Act (FACA) is also in some difficulty under the new FDA regulations. First, an advisory committee, we learn, is not limited to the giving of advice at the FDA. Despite the provision of the FACA that "advisory committees shall be utilized solely for advisory functions," [13] the FDA advisory committee can also serve as a Public Board of Inquiry for the purpose of adjudication and decisionmaking.[14] There is, I suggest, already sufficient confusion about the role of advisory committees at the FDA in the minds of the members, the agency personnel and in some cases, the Congress. Control of these committees under the Act will inevitably be diluted and their stature clouded if they become multipurpose entities.

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In contrast to the firm position taken on the secrecy of transcripts or advisory committee deliberations, the FDA regulations are schizophrenic with respect to the confidentiality of safety and effectiveness data. As the FDA recognizes,[19] these data are protected as trade secrets under the Food, Drug and Cosmetic Act.[20] Nevertheless, when these data are involved in a hearing, they will hereafter be "on public display" and may be examined but not recorded or transcribed "verbatim." [21] I recognize the difficulty which the FDA has faced in reconciling its objective of effective public participation with the statutory prohibition against *revealing* (not just copying) trade secrets. But a statutory prohibition cannot be discarded by agency fiat. The balancing of interests, particularly of this magnitude, lies at the heart of the legislative function. FDA's discretion in this balancing act has been explicitly limited by statute. If it's time for a change, the Congress—not the Commissioners—should see to it. The FDA, like any other agency, should not enjoy the exercise of unencumbered discretion by default of any other branch of government.

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TESTIMONY OF JOEL E. HOFFMAN, WALD, HARKRADER, AND ROSS

Mr. HOFFMAN. My name is Joel E. Hoffman. I am a partner in the Washington law firm of Wald, Harkrader, and Ross, where a major part of my practice is in advising and representing companies regulated by the Food and Drug Administration. It is an honor to be invited to address this subcommittee in its examination of FDA's performance in fulfilling the purposes of the statutes administered by the agency.

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[13] FACA, § 9(b).
[14] 21 C.F.R. § 2.20(d).
[15] 21 C.F.R. § 2.314 and 2.316(a)(8).
[16] The FDA has been upheld on this question by one court in Smart v. FDA, No. C–73–0118–SW (N.D. Calif. 1974).
[17] NLRB v. Sears Roebuck & Co., —— U.S. ——, 43 U.S.L.W. 4491, 4496 (1975); Renegotiation Board v. Grumman Aircraft Engineering Corp., —— U.S. —— 43 U.S.L.W. 4502, 4507–4508 (1975).
[18] Hearings on the Use of Advisory Committees by the FDA before a Subcommittee of the House Committee on Government Operations, 93rd Cong., 2d Sess. (1974) at 143.
[19] FOFA Regulations, Preamble, ¶ 252–257, 34 F.R. 44634–35 (Dec. 24, 1974).
[20] 21 U.S.C. § 331(j).
[21] C.F.R. § 2.5(j)(2).

The public accountability of government is one of the most fundamental characteristics of our political system. Periodic oversight hearings like these are therefore of the utmost importance in keeping the Congress, and through it the public, informed on the policies and procedures adopted by government to implement basic legislative mandates.

Although in his invitation the chairman indicated the subcommittee's desire to learn the perspective of regulated firms on the way in which FDA performs its functions, I must state at the outset that today I speak for myself, not as the representative of any company or group of companies. As one familiar with the perspective of such firms, perhaps I can describe that perspective in a manner helpful to the subcommittee. But any opinions I may express are solely my own. They are in no part the responsibility of, and should in no way be attributed to, any past or present client of my law firm.

Turning to the subject at hand, it should be said at the outset that for almost 10 years now, FDA has pursued its statutory mandate with a growing vigor, innovativeness, and determination which is perhaps unmatched by any agency of the Federal Government. Its leaders have sought to exploit the agency's regulatory powers to the fullest, and have devised a variety of new regulatory techniques, with the intent of providing as much protection as possible to the citizens of this country in an aspect of their daily lives where, as the Supreme Court noted more than 30 years ago in the *Dotterweich* case (*United States* v. *Dotterweich*, 320 U.S. 277 (1943)), they are largely unable to protect themselves.

The same regulatory vigor and creativity, however, have exposed some fundamental issues of governmental structure which lie at the heart of this subcommittee's concerns. One of these issues is presented by the fact, rarely mentioned in my experience, that FDA is not a so-called independent regulatory agency in the extraconstitutional fourth branch of Government, but as a constituent unit of the Depart- of Health, Education, and Welfare is part and parcel of the executive branch. Its powers are those conferred by statute upon the Secretary of HEW, a member of the President's Cabinet, delegated to FDA by departmental regulations. The issue this presents is whether it is proper or desirable for an executive department to exercise the sort of quasi-legislative power commonly conferred upon independent agencies, such as the Federal Trade Commission, as arms of the Congress.

A second issue arises out of the medical and scientific nature of so many of the issues confronting FDA. The disciplines which must be mastered to resolve such matters are not part of the working kit of most government administrators. The talents necessary for success as an administrator and as a medical scientist are not frequently combined in the same person. Although in recent years the public has been fortunate to obtain the services of just such versatile leaders for FDA, the agency has sought further to meet the problem by rapidly increasing its reliance upon outside expert advisory committees for difficult medical and scientific decisions. The comprehensive rules of practice and procedure recently promulgated by FDA promise even more of the same. The issue thus presented is whether this course comports with the basic principle of publicly accountable rather than private government. We in this country have always been resistant to the private exercise of governmental power, and experiments along that line such as

the NRA of New Deal days have only confirmed the wisdom of the principle.

The third question, simple but basic, which can be asked with reference to all regulatory agencies is whether the agency is adhering to the mandates laid upon it by Congress in the various statutes administered by it. In FDA's case, the question is sharply posed by many aspects of such recent agency actions as the new rules of practice and procedure, and the recently proposed regulations on "me-too" drugs. In one provision or another, these regulations illustrate three ways in which agency action may depart from a governing statute under the umbrella of authority to issue regulations "for the efficient enforcement of the act," a phrase whose simplicity is equalled only by its elasticity.

First, distinctions carefully drawn by the statute among various kinds of cases and among different procedural situations are ignored and obliterated. Examples are the statutory distinctions between adjudication and rulemaking, between antibiotics and other drugs, between new drugs and drugs no longer new.

Second, entire regulatory programs are created on the basis of no substantive statutory provision whatever, merely because the Commissioner has concluded that such a program would be in the public interest. The over-the-counter (OTC) drug review and the proposed scheme for regulating "me-too" drugs are only two examples.

Third, straightforward statutory language is interpreted in unusual and unobvious fashion for the purpose of justifying a policy judgment of the Commissioner, rather than providing a guide to the exercise of policy judgment, to the point where one is put in mind of Humpty-Dumpty's philosophy of linguistics in the Lewis Carroll fantasy "Through the Looking Glass"—that is, a word means what one wants it to mean, no more and no less. There are limits to what can be found in terms such as "safety" or "approval" which FDA has yet to recognize.

A final aspect of FDA's new procedural regulations which should concern this subcommittee has to do with the institutional relationship between administrative agencies and the courts. Chief Judge Bazelon of the Court of Appeals for the District of Columbia Circuit has characterized this in the *WHDH* case (*Greater Boston Television Corp.* v. *FCC*, 444 F. 2d 841 (District of Columbia Cir. 1970), cert. denied. 403 U.S. 923 (1971)), as a partnership in furtherance of the public interest. In this partnership, however, some matters are inherently the province of the courts, such as ripeness of agency action for judicial review, standing to seek review and whether the preconditions for seeking review such as exhaustion of administrative remedies have been satisfied. Yet the new FDA procedural regulations appear not only to state agency policy as to what arguments it will present and what position it will take as a litigant, which is surely admirable, but also to impose those views upon the courts through these so-called binding regulations having the force and effect of law. Indeed, these provisions seem designed to operate to compel acquiescence in the agency's views by parties before it, and thus to deprive the courts of adversary presentations on legal issues of great complexity.

I know of no other agency which has attempted to determine through rulemaking which agency actions are reviewable, in what

court, and at what stage of the proceeding. No less than the legislative branch, the judicial branch of our Government is entitled to have its constitutional role respected by agencies of the executive branch such as FDA.

All these issues are proper subjects of concern by Congress, but also should be considered by FDA itself in a mood of reflection detached from the urgencies of specific demands for action and particular programs devised in response. Each of the three branches of Government, not just the judiciary, has its own independent responsibility to evaluate the constitutionality of its action. Adherence to the separation of powers mandated by our basic constitutional structure should be high on FDA's list of priorities, along with its day-to-day statutory missions. Perhaps legislative hearings such as these will encourage the agency to renew its attention to these constitutional responsibilities.

That concludes my prepared statement. I would be glad to answer any questions.

Senator ABOUREZK. Thank you all for very good statements.

I have some questions I want to pose, and you can decide who will answer them.

Can you suggest any change, constructive changes in the legislation under which FDA operates which would improve its efficiency and facilitate dealing of both your industry and consumers with that agency?

Why do we not do that at another time and place? I am very much interested in proposing legislation which would rectify—we are concerned with the constitutional balance in this subcommittee—that particular aspect of FDA operations. And we would welcome your suggestions with respect to drafting that legislation brought out by your experience.

So let us delay that until you can discuss it with the staff.

In representing your clients before the FDA, what experiences have you had with FDA's enforcement practices and procedures?

Mr. MCMURRAY. I am not certain exactly what the Senator is after. I can merely say that once the agency gets down to coming to grips with the question and after certain administrative delays are gotten out of the way, my experience has been largely a good one—and even though occasionally we have had to go to court with the agency, I find that once in the court, litigation proceeds in a very professional manner.

Senator ABOUREZK. You mean on their part?

Mr. MCMURRAY. I hope on both parts, Senator. But what I'm trying to say is that once the issues are framed, I find that it can very easily go with the agency. It is getting those issues framed and moving around in the bureaucracy that is troublesome.

Senator ABOUREZK. This morning we discussed the fact that the act places jurisdiction in different courts for appeals of certain FDA actions. What problems does this present for you?

Mr. TEMKO. The specific point raised this morning—that there is a slight difference in some of the current provisions as to what court has jurisdiction—I don't think is of any great significance. And I gather that Mr. Merrill did not think so either. I believe the major consideration on what court you go to is more in the context of whether the FDA has constructed major programs which are not in the statute and for which no court appeal provision is contained in the statute.

There is consequently no logical consideration of, or provision for, what type of jurisdiction review should be had. The example I gave earlier is of particular interest from a legal point of view, in the sense that you have undertaken a complete review for the first time since the original food and drug law was passed in 1906, of every over-the-counter drug on the market. But since the agency made up the program, there is absolutely no provision in the act dealing with court review. Consequently, this is not a question of a minor variation from other provisions of the act. The agency has said, well, we are going to have to provide for some sort of judicial review, and we will simply say that you can go to a district court. Now, perhaps review from OTC decisions should be in a district court. I guess others might take the view the review should more appropriately be in a court of appeals, as in the case of most agency proceedings on a record. My thesis is simply that this is too basic a question to have to guess as to what type of court review exists.

Now, I doubt—my conferees may have some different views—I doubt whether you can go back and start the OTC review all over again. It is well underway. But I have mentioned briefly in my statement the FDA's proposed new program for "me too" prescription drugs, and Mr. Hoffman also referred to it. Instead of allowing the agency on its own to construct another basic new program—and the proposal for "old drug" monographs is a basic program—perhaps they ought to be told that they should come to you with some legislative proposal as to how this is to be handled. And until FDA comes to Congress with a legislative proposal, and new legislation is adopted, the agency should comply with the present provisions of the law.

But once again there is currently developing a situation where there will be another basic new FDA program with no provision for it in the statute, and again you will have questions as to how the program is to be implemented, what will be done during a transitional period, and what sort of judicial review should be involved. And there is nothing in the statute to indicate how Congress wants to handle it.

Senator Abourezk. Are there any procedures that you followed in the OTC drug review?

Mr. Temko. I beg your pardon.

Senator Abourezk. Are there any procedural regulations of any sort that pertain to the OCT review?

Mr. Temko. There are procedures that are followed. There are some regulations. And as each panel goes on with its work, further procedures are refined. So there are some procedures. However, these are very much ad hoc and they change, and there have been difficulties with many aspects of the procedures. For example, I think the whole question of the function of the nonvoting members on the panels is unclear. I don't think industry is entirely satisfied with the function of its members. Clearly, as Ms. Greenberger said, the consumer groups do not appear completely satisfied with their members. The current regulations make some attempt to take care of that. But again I think it is now a matter of patching up the OTC program rather than having a program where all these important matters are legislatively determined before the program is commenced.

Mr. Hoffman. If I might add a word to that, the problem with the OTC review and its procedures is not so much that the procedures were not laid down by Congress. That seems to me the sort of detail

which ought to be left to agency rulemaking. Getting out of these matters is exactly why you do delegate regulatory authority. The point is rather that the absence of any FDA procedures for such a program until the OTC program was created, and the lack of any fundamental criteria laid down by Congress for such matters as judicial review, only highlight the fact that the agency is really proceeding here pretty much on its own, making its own policy, not carrying out anything that could fairly be called a policy laid down by Congress, except in the most general—really empty—kinds of phrases such as "protecting the public health." Now, the phrase "public interest," of course, is used in any number of regulatory statutes, particularly with regard to independent agencies, which do operate pursuant to such language in their enabling legislation. But the content of the public interest in those contexts is usually delineated in other provisions of the statute, by the factors which are laid out by statute for the agency to consider. And you can find nothing of that kind in the Food and Drug Act which might support such a monumental undertaking as the OTC review, or for that matter the program for regulating "me-too" drugs. If I can turn to these for just one second, there is a perfect illustration arising out of the need for judicial review of FDA decisions in these two areas, which shows how far beyond any concrete statutory mandate the agency has gone.

Section 505 of the Food and Drug Act, which is the NDA provision, provides that review of an agency decision refusing to approve an NDA or withdrawing approval of an NDA can be sought by the "applicant" in a court of appeals. Well, that is a very specific phrase. The "applicant" may seek review. The agency has now advised us through rulemaking (and it has been upheld in this, it must be said, by the Supreme Court) that decisions on particular NDA's of particular applicants also have a concrete effect on the similar products of other manufacturers who are not applicants under the NDA. They are bound by an order withdrawing approval of an NDA, but they are not "applicants." How do they seek judicial review, for which "applicants" go to the court of appeals? They can't. The court of appeals is a court of limited jurisdiction. So they have to go to a district court, which is the court of general jurisdiction on questions arising under the Federal laws. And we have the extraordinary spectacle of the same order being subject to review both in a court of appeals as to some affected parties, and in a district court (possibly in some other circuit) at the behest of others. It is very unlikely that Congress would have created such a bifurcated scheme had it addressed the problem.

Senator Abourezk. I wouldn't be too sure of that.

Mr. Hoffman. I said unlikely, not impossible. And the fact that we now find ourselves having had to improvise such a scheme, which FDA has attempted to smooth out somewhat via its regulations, suggests very strongly to me that the whole program of applying NDA decisions to "me too" products is beyond anything Congress originally had in mind. It may be that this program is a very good idea, and that we ought to have class adjudication or that we ought to have rulemaking for classes of drugs. But that is only FDA's decision at this point and not a decision of the Congress. The difficulties with judicial review just highlight to me the disparity between what the statute provides and what FDA has done.

Senator Abourezk. Ms. McGrew commented briefly in her statement about the problems of presenting oral and written testimony at the hearing. Does anybody else have any further comments on that?

Mr. Hoffman. Well, there have been so few hearings at FDA that it is very hard for me to say how difficult or easy it might be. It is certainly true that the new procedural regulations evidence not merely a bias against oral testimony, but a firm desire to do away with it wherever this can be done without inviting reversal by the courts. It seems to me that this pathological agency fear of hearings has come out of some unfortunately protracted proceedings which have occurred over the last 10 or 15 years. And I think it can be said that no other agency would have tolerated what occurred. The Federal Power Commission regularly conducts massive ratemaking and certification proceedings with dozens or hundreds of parties. They manage to do it, they manage to get through it, and nobody really seems to think that it is impossible. They may wish the process to be improved further, but it is not considered impossible to do this if proper control is exercised. FDA has simply thrown up its hands and concluded that there is no way you can hold a hearing on a matter of great importance or complexity involving a large number of parties, and therefore they propose not to do it. Mr. Merrill in his prior incarnation as a professor of law commented 2 years ago in an FDA procedural rulemaking where the NDA approval regulations were taken up that the requirements for obtaining a hearing record like the charter of an agency which intends to hold no hearings at all. I don't know whether he has changed his views. I would not presume to ask him whether he has changed his views. But his statement was accurate then, and it is accurate today.

Senator Abourezk. In your experience in dealing with FDA, do you believe tht the agency has gone beyond its statutory authority and the Federal Advisory Committee Act in terms of delegating its decision-making authority to advisory committees?

Ms. McGrew. I think it would be too easy to conclude that it has or has not done so by counting the number of recommendations which it has or has not adopted. As hearings before congressional committees indicate, the agency simply can't win on this basis. If it rejects the recommendations of advisory committees, it does so at its risk, and you hear criticism that it has rejected much scientific and expert knowledge on the subject. If it accepts recommendations, it is accused of having delegated too much of its authority. I think it is hard to know exactly what goes on in the mind of the Commissioner when advisory committee recommendations are reviewed. I would think it would be helpful, as I indicated in my statement, to be more fully aware of what occurs in advisory committee deliberative sessions so that we can appreciate what thought has gone into the recommendations. Then we can evaluate the basis of the advice and conclusions that have been reached.

Senator Abourezk. Do you believe that FDA has handled satisfactorily the trade secrets problem in section 4.61 of the public information regulations?

Mr. McMurray. I think that the thrust of the regulation or the effect of the regulation in which the Food and Drug Administration sets itself up in the first instance as making the threshold judgment as to what is or what is not a trade secret is wrong. There are many instances, like it or not, as the Commissioner stated, that he was very

liberal about these things and about letting out information. I think the regulation going beyond reason in the statement that by the time a trade secret is given to the public under the procedural regulations, the affected owner of that trade secret has precious little recourse. It has been suggested, and will be suggested by an American Bar Association Committee which is working on this, that prior notice of the dissemination of certain things that are or should be trade secrets given to the affected party with a time requirement set to come in and make some kind of presentation as to whether it is or is not a trade secret. I think the regulations in that part need some real thinking.

Senator Abourezk. Well, those are all the questions that I have.

I want to express my thanks to all of you, and my apologies once again for the innumerable delays.

The hearing is recessed until Wednesday at 9:30.

[Whereupon, at 3:50 p.m., the subcommittee was recessed, to be reconvened at 9:30 a.m., Wednesday, July 23, 1975.]

Statement of Anita Johnson, Public Citizen's Health Research Group

I am Anita Johnson, an attorney with the Health Research Group, a consumer research and advocacy organization funded by voluntary donations to Public Citizen. I have been asked by the subcommittee to make general comments about the procedural regulations published by the Food and Drug Administration, May 27, 1975.

Hearing procedures

The formal procedures traditionally used by FDA to hear disputes have been time-consuming, expensive and low in substantive contribution to decision-making.

Formal hearings on peanut butter ran four and a half months. The hearing transcript was 7,736 pages. Much of the debate centered on whether peanut butter should contain 87 percent or 90 percent peanuts. FDA formal hearings on vitamin pill limitations ran intermittently for over two years. The transcript consumed over 32,000 pages. Hearings on carbon tetrachloride, a substance known to be lethal, ran for two years, during which time the product was on the market. The danger of this product had been common knowledge in the scientific community for years. The Heffron Report commissioned by the National Commission on Product Safety comments: "If a formal rulemaking proceeding to ban a product whose severe hazards are virtually common knowledge can take more than two years, one can only wonder how long would be needed for completion of a proceeding involving more controversial issues."

The Report states: Administrators apparently fear that a major conflict in rulemaking or enforcement would tie up so much of the agency's resources that its ability to press its program would be hamstrung.[1]

Formal evidentiary hearings a la FDA are the perfect instrument for those who would obfuscate and delay agency action. Moreover, the mere availability of formal hearings has put FDA in the position of having to compromise its actions to *avoid* holding formal hearings. The formal hearing system allows industry to blackmail FDA in this way: either compromise your position or we'll request a formal hearing.

Last, formal hearings as held by FDA in the past, have been poor vehicles for substantive input into decisions, because the issues at stake are really *policy* issues rather than *factual* ones. A formal evidentiary hearing, conducted orally by lawyers and presided over by an administrative law judge, with full cross-examination of witnesses, and formal findings of fact and law on the record introduced at the hearing, is an awkward way to consider whether it is wise policy to ban a drug acknowledged to cause cancer in animals or to set up an emergency permit system for tomato canning. As Kenneth Culp Davis, perhaps

[1] From Laden, "FDA Rule-Making Hearings," *George Washington L Rev*, 40, 4 (May 1972) 726, 733.

See also, Hamilton, "Rulemaking on a Record by the Food and Drug Administration," Administrative Conference of the U.S., 1971.

the outstanding expert in administrative law, has stated: "A trial is designed for resolving issues of fact, not for determining issues of law, policy or discretion. In rulemaking, the method of the trial has no place except where specific facts are at issue, and even then it should seldom be used when the disputed facts are legislative." "The Requirement of a Trial-Type Hearing," 70 *Harv. L. Rev.* 193, 199 (1956), as quoted in Laden, 736. On the other hand, such hearings may be more useful for purely factual disputes, such as whether or not a certain study demonstrated that a drug caused cancer in animals. The overall issue of whether a drug or food additive is "safe" is really a policy judgment, since it is not a factual judgment in terms of being true or false, but is a weighing of the available facts on the benefit side with the facts from the risk side. The judgment will be different depending on the social values of the decision-maker.

For the above reasons, we approve of FDA's attempts in recent years to restrict the number of formal evidentiary hearings. FDA has determined that hearings not be held unless there is a question of fact at issue—as opposed to a question of law or judgment. The May procedural regulations state that a formal evidentiary hearing will not be held unless there is a genuine issue of fact capable of being resolved by available and specifically identified, reliable evidence; a factual issue which, if resolved in the way sought, may alter FDA's judgment on the entire matter. s. 2.113 (b).

A 1973 Supreme Court case, *Weinberger v. Hynson et al* 412 U.S. 609 ruled that FDA was statutorily required to hold formal hearings on new drugs only if the manufacturer first demonstrated that it had affirmative, reliable evidence to discuss at the hearing. Earlier cases had established that such evidence would have to be adequate and well-controlled. *American Cyanamid Comp. v. Richardson* 456 F2 509, 513 (1st cir. 1971) ; *Upjohn v. Finch* 422 F2 944, 955 (6th cir. 1970). In ruling on the need for a formal evidentiary hearing, a 1975 case, *National Nutritional Foods Assn. v. Weinberger* —— F 2 —— (2d cir.) held that agency rulemaking on vitamins A and D toxicity did not need to be preceded by a formal hearing: "Since the decision did not turn on precise factual issues or on the credibility of witnesses but represented a judgment based upon consideration of relevant medical and scientific data, we doubt that a trial-type adversary hearing would have shed any further light on the question." [2] The courts have not ruled on the exact language of the May regulations, but in view of the past cases, it is likely that the courts will continue to endorse FDA's efforts to narrow the occasions for trial-type hearings.

In view of the awkwardness, expense and unsuitability of trial-type hearings, and the court's endorsement of FDA's attempts to limit their number, we are confused as to why the witnesses from the private bar believe that FDA's attempts to restrict formal evidentiary hearings are unwise and unlawful. Perhaps their beliefs stem from their success in the past in using these formal hearings or the threat of hearings, to delay or stymie agency action on behalf of their food and drug industry clients.

For those situations where there *are* substantial and material issues of fact, FDA is attempting to make formal evidentiary hearings more manageable. We support the requirement in the May regulations that evidence be presented "to the maximum feasible extent through written submission, including written direct submissions," through written cross examination, etc. The factual issues in these hearings are technical and complex, and are not really amenable to oral presentation. Moreover, oral presentation is time-consuming, frequently of lower quality economy and precision than written work. In Spring 1974, I represented Dr. William Crosby in a trial-type hearing on the issue of whether extra iron should be added to bread. Involved were elaborate evaluations of statistics, toxicology studies, etc. In my view, no administrative law judge could humanly master such technical matters by ear. All of the points raised and considered at the hearing could have been done with greater clarity and economy in writing.

[2] *Sterling Drug v. Weinberger,* 503 F2 675, cited by Mr. Temko as support for more formal hearings, was superceded by a decision on the same case, *Sterling Drug v. Weinberger,* 509 F2 1236, wherein the court affirmed FDA's judgment that no adequate, well-controlled evidence had been submitted to secure the right to a hearing (but extended the deadline to submit such evidence). In *Edison Pharamaceuticals Co. v. FDA,* 513 F2 1063 (D.C. Cir., 1975) the Court affirmed the threshold standard FDA requires for hearing requests, and affirmed that the plaintiff did not meet that standard, but nevertheless made an "exception" and ordered a full evidentiary hearing "on all relevant issues relating to petitioner's NDA" apparently under the court's general equity powers, because of the special circumstances of the case. That case does not, in our view, support the view that FDA contravned the meaning of the statutory hearing requirements.

The opportunity for a *well-designed hearing* on disputes with FDA is absolutely essential for the rights of the private parties, and to assure that FDA operates wisely in the interest of the public. Therefore, sound options to formal evidentiary hearings must be developed—hearings geared for the assessment of policy matters, matters of judgment. I believe that *the major options developed by FDA thus far are poor.* First, there is the "Public Board of Inquiry." According to the May regulations, this Board may be used in place of a formal hearing when a party with a statutory right to a formal hearing consents, and for all other disputes if FDA deems it appropriate. The Public Board of Inquiry is a group whose members must be picked from nominations submitted by private parties and the FDA. The private party has veto power over any FDA employee chosen to be a member of the Board. s. 2.202.

The fatal disadvantage of this system is that the private party wishing a hearing gets to select its own judge. This is certainly unprecedented in the courts, and to our knowledge unprecedented in other administrative agencies. In general, governmental decisions, made on behalf of the public and paid for by the public, both in terms of the administrative costs and the health repercussions, must be made by public officials. Outsiders are not as accountable for their decisions as civil servants are, they are frequently ill-informed about regulatory matters—no matter how high their technical competence—and they are not subject to the strict conflict of interest prohibitions that civil servants are. Not only does the Board of Inquiry make the initial decision on regulatory matters, but its decision, under the FDA scheme, becomes final, absent action on the part of the Commissioner to stop it.

The second major option is a "Public Hearing Before an Advisory Commitee." This option is deficient for the same reasons. It is a group of outsiders, unaccountable to the public, individually or as a group, lacking the regulatory skepticism which comes with regulatory experience and lacking the conflict of interest prohibitions of civil servants. FDA advisory committees in some areas are constituted from nominations by the regulated industry, the AMA, etc., so the problem of choosing the judge is also present. In addition, some of these committees have members who are employed or supported by industry.

Ideal in our view would be hearings before an official who is a civil servant. Such hearings would be for the purpose of hearing objections to the order or regulation contested, and findings by the hearing officer would not be based solely upon the record adduced at the hearing, so that FDA would not have to re-present its case at the hearing itself. Only those who object would make presentations. The hearing would be open and a transcript would be made. All interested parties would have an opportunity to participate, although the principal party should have more time. Since the crux of this hearing will be policy judgments rather than factual disputes in the narrow sense, oral testimony would be appropriate in addition to written testimony, although oral testimony would not be necessary. Cross-examination of agency officials by the principal party could occur, but this should be restricted to cross-examination which could not occur in written form, and should have stringent time restrictions. Opportunity for cross-examination of witnesses in writing by other private parties should be accorded. This hearing would be similar to a true legislative hearing. In some respects it is similar to an informal public hearing held by FDA on the subject of Over-the-Counter antacid drugs in January 1974, a hearing which was eminently successful, in our view, inarticulating the issues in dispute and presenting them to FDA decision-makers.

Integrity of Agency Files

In 1972, the Health Research Group discovered, through a questionnaire sent to FDA medical officers—the M.D.'s responsible for evaluating new drug information and making an initial decision on whether or not the drug is safe—that alteration of agency documents and removal of information unfavorable to particular drug products had occurred in more than a few instances. In August 1974, testimony by medical officers at the Senate Subcommittee on Health hearings on FDA confirmed that this was a continuing problem. The frequency of such occurrences is not known. However, since the reported cases all involved deletion of unfavorable information, careless or dishonest record-keeping may mean that some approved drugs should not have been approved.

FDA's new regulations take steps to improve agency record-keeping, in that they prohibit deletion or alteration of records, and prescribe instead that alterations be made by amendment, prescribe that all scientific controversy be

reflected in the file on an individual product, and give every employee the explicit right to have his or her views included in the file.

In addition, they require that when new information relevant to a pending drug decision is received by the agency from the manufacturer, it be submitted initially to the medical officer. This should curb the past fears of medical officers that high-level FDA officials made decisions over their heads on the basis of come-lately submissions and unevaluated lobbying material submitted by industry in private session.

Citizen's Petitions

The new regulations have an explicit provision for petitions on orders and regulations by any interested party. Heretofore, there has been no formal way for consumers groups to open up questions on individual products, and no obligation on the part of the agency to respond or consider such petitions.

The Health Research Group has petitioned FDA on individual products. January 2, 1973, we petitioned to stop certifying of red dye #2. March 1974 we petitioned to limit use of the cancer-causing drug metronidazole (Flagyl). We have received no response to these petitions. On the other hand, we have also petitioned FDA on rulemaking, where FDA is legally obligated to consider our petition, and have received no answers on these, either. May 1973 we petitioned FDA for regulations to require the completion of animal testing before drug testing in humans began. Dec. 1974 we petitioned FDA to declare all Intra-uterine contraceptive devices "drugs", so that they would be tested before marketing. No answer.

Clearly, improvement is needed in FDA's willingess and ability to consider the petitions of non-industry parties, and we are hopeful that the citizens petition procedures will improve things. However, needed with the citizens petition, is the addition of concrete deadlines.

Federal Advisory Committee Act

The FDA has regularly closed the vast majority of its advisory committee proceedings under the rationale that the Federal Advisory Committee Act allows committee "deliberations" to be secret. This defense is under litigation at the moment by us. Suffice to say that we believe that closed advisory committees make advisers careless, unaccountable, and vulnerable to manipulation by both FDA officials and industry representatives, with the result that they make sloppy or poor health decisions. The new FDA regulations continue the old practice of secreting advisory committee proceedings.

Freedom of Information

Public access to data in agency files on the safety and efficacy of drug products is a major health priority. Currently, FDA secrets this material under the reationale that it is "trade secret" material exempted from public disclosure under section 4 of the Freedom of Information Act. So long as this crucial data is secreted, FDA will be vulnerable to undue influence by manufacturers seeking to market their products, with the result that drugs may be approved under conditions when they should not be.

Enclosed with this statement are two articles which detail further my views on this subject.

In testimony before this committee Mr. Raymond McMurray stated his view that whenever a request for information is made FDA should consult the manufacturer who submitted information prior to release. He said, "It has been suggested, and will be suggested by the American Bar Association Committee which is working on this, that prior notice of the dissemination of certain things that are or should be trade secrets be given to the affected party with a time requirement set to come in and make some kind of presentations as to whether it is or is not a trade secret." *In fact*, the American Bar Association Committee did not endorse Mr. McMurray's view. I was at each of the meetings of the committee he refers to, and the committee made an explicit decision ***not*** to take any position on "prior notice."

CONGRESSIONAL OVERSIGHT OF THE ENVIRONMENTAL PROTECTION AGENCY

WEDNESDAY, JULY 23, 1975

U. S. SENATE,
SUBCOMMITTEE ON SEPARATION OF POWERS,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:35 a.m. in room 2226, Dirksen Senate Office Building, Senator James Abourezk (chairman of the subcommittee) presiding.

Present: Senator Abourezk.

Also present: Irene Margolis, staff director; and Carl Tobias, counsel.

Senator ABOUREZK. The subcommittee meeting will come to order. This is the second day of hearings on oversight of Federal agencies. This morning the first witness will be the General Counsel for the Environmental Protection Agency, Robert V. Zener.

TESTIMONY OF ROBERT V. ZENER, GENERAL COUNSEL, ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY WILLIAM F. PEDERSEN, ATTORNEY, EPA

Mr. ZENER. I have Mr. William Pedersen with me who has experience in the matters we are going to talk about.

Mr. Chairman and members of the subcommittee, I am pleased to be here today to testify on the administrative procedures EPA uses to implement our regulatory programs. I will be brief in my prepared statement so as to leave as much time for your questions as possible.

EPA is basically a rulemaking regulatory agency. Our three major areas of responsibility are air pollution control, water pollution control, and control of pesticides. We also have regulatory authority with regard to noise control, the protection of drinking water, and the control of radiation hazards.

Only for pesticides does the statute give a central role to formal hearings before an administrative law judge. For our other regulatory authorities, our procedures are patterned on rulemaking under section 553 of the Administrative Procedure Act.

In general, this act requires any rule which the Agency is thinking of adopting to be issued in proposed form, and public comments are invited, and when the final rule is issued, the Agency must explain why it did or did not accept the major points those comments raised.

We believe these procedures have worked well. If formal, courtroom type hearings had been required, EPA no doubt would have been

severely hampered in putting the air and water pollution control statutes, most recently enacted by the Congress in 1970 and 1972, into effect. In this connection, I would refer the subcommittee to an article by Professor Hamilton, "Procedures for the Adoption of Rules of 3 General Applicability; the Need for Procedural Innovations in Rulemaking." 60 Calif. L. Rev. 1276 (1972). He refers specifically to the experience of the Food and Drug Administration:

"The 16 formal hearings that were held during the last decade vary from unnecessarily drawn-out proceedings to virtual disasters and in not one instance did the agency complete a rulemaking proceeding involving a formal hearing in less than 2 years."

In two instances more than 10 years have elapsed. The average time lapse was roughly 6 years—4 years. When one considers the time constraints on EPA and the volume of regulatory action we are required to take, it is apparent we could not have done all this using formal courtroom type proceedings to promulgate our rules.

It is instructive to look at the experience that EPA has had with formal hearings in the pesticides area where we are required to hold formal adjudicatory hearings in connection with the cancellation of pesticide registrations.

We only completed two hearings in connection with aldrin and dieldrin and with DDT. Each hearing took more than 1 year to complete.

Although the informal notice and comment procedures have worked well, we do not believe they are perfect. The evolution of our rulemaking practices over the past 5 years has been steadily toward greater procedural formality. For example, we now provide much more complete and earlier disclosure of what we plan to do and why we plan to do it. We aim at full disclosure at the time a rule is proposed.

A good example of this procedure is our promulgation of the effluent water pollution guidelines. We asked an independent consulting firm to give us a report on the industry which will be the subject of the guidelines. These are guidelines that specify the amount of pollutant discharge that will be permitted from particular types of industries under the Federal Water Pollution Control Act.

When the consultant has given us a report that describes the type of wastes produced, the feasibility, the particular types of control technology that are feasible, we take this report and distribute it to the industry and to interested environmental groups.

We get comments on that report. It is only after we have gone through that process that we formally propose a regulation in the Federal Register and start the administrative procedure requirements.

This more open approach to the rulemaking was largely triggered by Judge Leventhal's opinions in the *International Harvester* and *Portland Cement* cases (*International Harvester Co.* v. *Ruckelshaus*, 478 F. 2d. 615 (D.C. Cir. 1973); *Portland Cement Assn.* v. *Ruckelshaus*, 486 F. 2d. 375 (D.C. Cir. 1973)). In those decisions, the court required EPA to let the world know in full at the time it proposed an action the facts on which the proposal was based and how those facts had been analyzed. Today we try to follow these principles in all our rulemaking.

Such disclosure tells the public and industry the basis for the agency's case and allows all parties time for review and analysis and an opportunity to point out any weak points.

The *Portland Cement* case makes clear that a rule should not be upheld if the Agency does not satisfactorily address the issues raised in public comments received by the Agency on the rule.

Often this approach alone has been enough to fully air the issues. That was true, for example, in the *Portland Cement* case itself, which involved new source performance standards under the Federal Clean Air Act. After the court had sent it back to us, our response to the remand, which was developed through these procedures, has just been upheld in all respects by the District of Columbia Circuit (*Portland Cement Association* v. *Train*, 513 F2d 506 (D.C. Cir. 1975)).

Sometimes, however, further probing of the issues may be necessary. There are many ways this can be done. For example, informal conferences with the affected parties can be held, either on or off the record, or legislative-type hearings can be conducted, or interrogatories exchanged. Any one of these can bring clarity to disputed matters without the cost in time and money of formal cross-examination.

In connection with our promulgation of effluent guidelines under the Federal Water Pollution Control Act, we held a 2-day hearing at which panels of experts representing industry and public interest groups and EPA discussed the various technical issues involved in our effluent limitations guidelines.

I think that was a very profitable venture and, indeed, the industry in its court suit challenging our effluent guidelines has raised no contention with respect to the adequacy of the procedures followed. They apparently concede that our procedures were in all respects adequate.

What I have said so far reflects the law and practice at present. But this is a changing field. The legal system has not adjusted completely to the tremendous growth in rulemaking which the legislation of the last few years has triggered.

In general, I believe the trend is still toward greater use of some formal procedures, and to even stricter requirements that the agency put all its cards on the table. At the same time, I believe the courts will try to make sure that any new procedures are less open to abuse by regulated industries and their lawyers than some procedures used in the past, such as the formal rulemaking procedures that the Food and Drug Administration used and had such unfortunate experience with.

In particular, I believe the next centers of attention in this regard will be the nature of the record in informal rulemaking and the relationship of the Freedom of Information Act to the Agency's obligation to make full disclosure.

I think greater attention has to be given to the defining of the documentation that agencies rely on when they issue rules. We must make sure that this documentation is available in one place so that it can be examined by the public, by the environmental groups, and by the affected industry, and that it may be examined in a timely fashion so that all these groups can adequately comment on the agency proposal before it is finally promulgated.

However, I would rather not speculate too much on the future. The case law has been developing so quickly and so satisfactorily in the past few years that I think the best thing to do for the present is just to let it go on developing.

Before closing, I would like to make a few remarks on the adequacy of public input to agency rulemaking. My own experience is this: I think the procedures for public input are fully satisfactory. In my experience, any environmental group that wants to participate in a rulemaking has ample opportunity to do so.

They can submit written comments after inspecting all our documentation and if they want to make an oral presentation, I know of no instance in which a request for a conference on the part of an environmental group has been denied.

That is not to say that there is not a problem here. I think there is a problem in connection with the adequacy of public input to our decisionmaking. The problem really seems to stem from the extremely technical nature of most of what we do. The fact of the matter is that in most instances the public interest groups don't have adequate resources to make a fully informed contribution to our rulemaking.

After all, when you are talking about what the proper technology is for the discharge from a kraft papermill or from a cane sugar refinery, generally speaking the only people who have intelligent comments to make on this point are the industry.

I think it is unfortunate that this is the case but I don't know how to solve it. Public interest groups don't have the technical expertise and the resources to address themselves to these particular questions; certainly constructing more elaborate procedures for public input won't cure the deficiency.

I don't really have a solution to this problem but I don't think constructing more elaborate procedures represents any solution at all. I think that finishes what I have to say. I would be pleased to answer any questions.

Senator Abourezk. The field structure of the EPA consists of 10 regional offices. Your Agency has been subject to strong criticism for lack of uniform implementation by the 10 regional offices. Do you concede that this is a problem?

Mr. Zener. I guess that is a problem but on the other hand we have also been accused of being too inflexible and not adjusting sufficiently to a local situation. There is always a balance to be struck.

On one hand, you have the danger of overdirection from Washington that would tend to lead to situations in which you are being insensitive to the complexities. On the other hand, the other danger is lack of uniformity.

Senator Abourezk. Don't regulations allow that kind of flexibility for different sized communities and other similar situations?

Mr. Zener. It depends on the regulations. Generally speaking, yes, and I think that is a good thing. Naturally when you allow flexibility, the inevitable corollary is some lack of uniformity.

It is a problem, but that does not lead me to the conclusion that we should impose greater uniformity from Washington than we have. It is one of these perennial problems of life that has to be dealt with.

Let me cite an example if I may. The effluent limitations guidelines that I referred to before specify the amount of effluent that can be discharged by industries.

We have a variance clause in our guidelines for the degree of pollution reduction that must be achieved by 1977. We have been criticized for having that variance clause by the environmental groups.

On the other hand, the industries have criticized us for attempting to achieve too much nationwide uniformity and for failing to recognize the variability that takes place from plant to plant.

I am not sure we have achieved the right solution. The point is that there are two sides to this problem.

Senator ABOUREZK. The President's message which accompanied Reorganization Plan No. 3 of 1970 establishing EPA made much of the fact that a single agency charged with handling environmental programs would be better able to coordinate environmental protection which was then scattered throughout the Federal bureaucracy.

To what extent has this proven to be a correct assumption?

Mr. ZENER. That is a difficult one to answer. I do know of situations where I think we have taken into account what might be called cross-media effects to a greater extent than would have been the case had we not been one agency.

For example, for certain industry processes, if you impose a certain type of water pollution control you increase the air pollution problem and vice versa. There are certain scrubbing techniques that increase the amount of water pollution that the industry discharges.

In the rules we put out, we have attempted to consider the impact on one media from control from other media. In addition, we have increasingly realized that the philosophy you follow in attempting to control certain types of pollutants ought to be the same regardless of whether you are talking about water or air or pesticide control.

The agency right now is trying to develop a uniform policy on the treatment of carcinogens. This would be a policy applicable whether the carcinogen is going through the water or the air or a registered pesticide. So I think the unification has led to some attempts to consider these problems in an intergrated fashion.

Whether these attempts have succeeded is a matter of judgment.

Senator ABOUREZK. Do you think that responsibility for areas of environmental concern, that presently are not entrusted to EPA, ought to be placed under EPA jurisdiction?

Mr. ZENER. That is a delicate question. I have not really thought about that enough to answer it.

Senator ABOUREZK. Are you referring to strip mining or other areas?

Mr. ZENER. Both. I might say this: The general feeling of the Agency right now is that we are terribly overburdened.

Senator ABOUREZK. You have enough political problems now?

Mr. ZENER. Political and administrative. I have not noticed any mood around the Agency to volunteer for additional responsibilities.

Mr. TOBIAS. In our hearings that we held on Monday, we discussed FDA's new procedural regulations. Extensive provision is made for ex parte communication with the agency. All such communications must be reported in a written memorandum placed in the file of the matter under consideration and made available to the public on request. I understand that EPA has considerable ex parte communications with representatives of the industries it regulates.

You pointed that out this morning in your testimony and Mr. Roisman alludes to it in the statement he is going to make this after-

noon. How does the Agency deal with the problem of ex parte communications?

Mr. Zener. We have not adopted a rule prohibiting ex parte communications or requiring that they all be placed on the record. It is our present thinking that there are sufficient safeguards in the requirement that every action, even regulatory action the agency takes first be proposed and open to public comment and, second, be based on some kind of record that is open for the public to see and, third, be fully explained by the Agency when it acts.

This is not a simple problem. If you adopted a rule that every ex parte communication had to be the subject of prior notice with an opportunity for all affected parties to participate, what you would be doing would be to convert the Agency into something closely resembling a court.

You would be judicializing the Agency's procedures. Perhaps this is best discussed in connection with a case in which I know we have had a controversy with Mr. Roisman. I have not read his statement but I suspect he refers to the issuance of a permit for a nuclear power-plant in New Hampshire.

The Governor of New Hampshire had wanted to know what was going on and asked for a briefing from EPA and from the industry. We briefed the Governor of New Hampshire. Now should we have said, "No, Governor, we can't talk to you until we first put a notice in the Register and if a lot of people show up, we may not be able to talk to you in your office." We may have to go to an auditorium and convert this into some kind of a public hearing.

EPA has been accused of not being responsive and accessible. I hate to think what the Governor of New Hampshire's reactions would have been if we had given him that response to his request for a briefing.

That is an example of the kinds of problems you would face if you in fact judicialized the Agency by saying that nobody can talk to officials of the Agency unless you first gave the public prior notice and made a record thereby converting each conversation into a mini-hearing.

On the other hand, I recognize that the existence of ex parte communications leads to some degree of public suspicion.

I think it is a problem, but I think you have to recognize that the degree of formality attendant to the type of rulemaking you suggest would entail would involve its own problems.

Senator Abourezk. EPA has been criticized because staff members at the regional and national levels take action which exceeds their authority. What procedures has EPA instituted to insure that the staff does not exceed limitations on their authority?

Mr. Zener. That depends on the program you are talking about. Under the Federal Water Pollution Control Act if the company or a public interest group is dissatisfied with a permit, they can appeal to the Administrator.

This is a mechanism whereby the actions of the regional offices can be reviewed and reversed if they have exceeded their authority.

I believe we have the same appeal procedure in connection with our programs for assessment of civil penalties under the Pesticides Act. Those are two examples. In other cases, there may be no formal appeal

procedure, but there are instances where people dissatisfied with regional actions have come to headquarters and in some cases obtained relief.

There is no single procedure because we run a number of different programs which all have different problems.

Senator Abourezk. We have received reports that the relationship between the EPA and many of the States is marked by considerable discord.

I understand that some State officials feel that they are left with no power whatsoever. They complain of having no freedom or flexibility and that EPA is heavyhanded in dealing with the States. Please comment on this and state what procedures you have established for administratively resolving the differences between regional offices and the States.

Mr. Zener. I have heard these complaints, too, and they may be justified in some instances. It is hard to say. I think you have to recognize that EPA is administering a number of programs in which—I think it is fair to say that a new concept of federalism is being tried out.

Instead of having the State and Federal governments run on parallel and largely unconnected tracks, the Congress is increasingly adopting statutes saying that the Federal Government lays down general standards and the States actually administer the program with some type of Federal overview.

One example is the Federal Water Pollution Control Act permit program in which the States actually issue the permits under a Federal overview which consists of Federal approval of State procedures and a Federal veto of major permits.

Another example is the Clean Air Act where the States adopt implementation plans which have to be approved by the Federal EPA. Whenever you adopt a program of this sort that involves the Federal Government reviewing and approving State programs, it is inevitable that you are going to have some disagreements and controversy.

If there were no disagreement and controversy, that would be a sign that the Federal agency was not exercising its overview function that it was charged with by the Congress. To a large extent, the complaints you are hearing are inevitable, an inevitable concomitant of a program in which the Federal agency is cast in a supervisory role over the States.

This kind of friction is inevitable. Now, I personally don't think that the friction has been greater than it ought to be. The States, under the Clean Air Act and under the Water Act, are in fact administering a large part of these statutes, and on the whole they are doing it pretty well.

The first part of my answer is yes, these complaints exist, but I think they are inevitable, and I don't think they are an unhealthy sign.

The second part of your question is what procedures exist to review these complaints. This depends on the program area you are talking about. In connection with approval of State programs for either implementing the Clean Air Act or the Water Act, the overall program approval comes from the Administrator. The complaints on those scores go directly to the top.

With regard to day-to-day relationships between the regional offices and the States, there are no formal complaint procedures. However, I can assure you that whenever a State administrator or a Governor is mad at something the regional office has done, he has no trouble making his complaints heard.

I should mention in this connection that under both the Clean Air Act and the Water Act, we have regular meetings with committees of the State administrators. I have attended a number of these meetings, and I can assure you that these gentlemen have no compunction about making their complaints known.

I don't think there is any need for establishing more formal procedures in this connection.

Senator ABOUREZK. How do you determine the validity of these complaints, and how quickly do you respond to them?

Mr. ZENER. Well, when we think the complaint is valid, the response has been pretty quick. Sometimes we don't think a complaint is valid, and the State does not think the response is quick enough.

As far as determining whether the complaint is valid, it is a matter of talking to all the people involved. There is no formal procedure that I know of. It is hard to generalize in this area because the problems are so varied. The contacts that EPA has in the States range from grant problems involving a particular municipality to a dispute over implementation procedures under the Clean Air Act.

Mr. TOBIAS. What about the specific situation, under the Water Act, where a permit provision might be written by the State and overridden by EPA. In that type of situation, what provision is made for appeal?

Mr. ZENER. I suppose you are referring to our power to veto individual permits under section 402 of the Water Act. Quite frankly, we have not developed appeal procedures in that area. Perhaps we should. There have been very, very few exercises of that veto power. Only one that I am familiar with that has resulted in litigation.

In that particular case, the lawsuit has resulted in some headquarters review of the action because the office of the general counsel in Washington handles the lawsuits.

I don't think that is a satisfactory way of reviewing the action. It may be that we should develop some procedures there.

Mr. TOBIAS. I think you may be disregarding what happens in practice where pressure has been brought to bear by the regional office and the State accedes. This leaves the regulated party with no real opportunity to protest.

Mr. ZENER. That is a problem. But on the other hand, remember also that setting up appeals procedures involves delay. By statute, EPA is required to say—I am sorry—to interpose an objection if it has an objection within 90 days of the proposed permit.

We have shortened that period to 30 days in most cases in connection with our transfer of the permit programs to the States. Now these deadlines are very important. There are thousands of permits to be issued and you can't keep the company dangling on the end of a string forever. You have to act quickly.

Appeal procedure, a formal appeal procedure, would inevitably involve violating those deadlines. So this involves a very real cost.

Mr. TOBIAS. One of the private attorneys who will testify notes in his opening statement that the time deadlines imposed in the statutes

which EPA administers present real difficulties for the Agency because it often must develop quickly the expertise to make complex decisions. The tight timetables in these statutes also place constraints on industries preparing comments for submission proposed rulemaking.

The upshot of this is that EPA may not end up with a finely tuned rule applicable to the particular situations.

One solution to this offered by the private attorney is more widespread use of variances. What is your reaction to this general statement and to the suggested solution?

Mr. ZENER. Well, I must confess to a somewhat ambivalent feeling about the statutory deadlines. When you are operating under one, it almost always seems oppressive and you always think that more time would be helpful.

On the other hand the bureaucracy is such that if the deadline does not exist in many, many cases, either no action would be taken or action would be interminably delayed. I can think of situations where our statute imposes no deadline and says as soon as practicable. In one particular case where that requirement was imposed in the spring of 1970 action has not been taken yet.

That particular action involves terribly difficult problems, but most of our actions do. If there is no deadline staring you in the face, the tendency is to study the problem some more because most of these problems can always benefit from further study.

So I am very sympathetic towards the congressional practice of imposing deadlines on the Agency. I think some of the deadlines that have been imposed are too tight but on the other hand most deadlines generally seem too tight because one tends to put the thing aside until the deadline is staring you in the face.

This is not only a practice with Government agencies. I think any lawyer involved in litigation finds himself staying up until the midnight before the brief is due preparing that brief.

Yes, the deadlines are frequently too tight; but no, I would not recommend not having them. As for wider use of variances, I tend to disagree. In connection with our effluent water pollution guidelines under the Federal Water Pollution Control Act, we inserted a variance clause for the 1977 requirement and my experience is that it has been very rarely used.

I am advised that the permit writers on the whole manage to find sufficient flexibility in the regulations as they are written to write permits that are, on the whole, realistic.

I think that the merit in such an approach may be attested to by the fact that generally speaking, we are getting a rather low percentage of appeals from the permits that are written. The general conclusion that I draw from this is that I don't think you need greater flexibility.

It is a conclusion that is admittedly subject to change.

Mr. TOBIAS. I am sure we shall hear from the private attorneys about that. You note that the courts will try to make sure that any new procedures are less open to abuse by regulated industries and their lawyers than some rules issued in the past.

Mr. ZENER. I referred to the unfortunate experience of the FDA with formal rulemaking procedures.

I think the courts as a result of that kind of experience have been reluctant to read statutes as requiring agencies to have formal adjudicatory hearings in connection with the promulgation of regulations.

A good example of that is the Supreme Court's recent decision in the *Florida East Coast Railway* case where they read a statutory requirement for a hearing in the Interstate Commerce Commission Act not to mean a formal hearing despite substantial arguments to the contrary.

I think that the courts will be sympathetic to our attempt to develop fair procedures that fall short of the formal courtroom type procedures: A full disclosure of documentation, informal technical conferences and full adequate explanation by the Agency of just what it is thinking and what it is doing.

Mr. Tobias. In line with what you have just said, one of the private attorneys who will testify shortly will say in his opening statement that where a complex technical regulation is concerned, EPA should be required to meet with a representative group of those subjected to the regulations for the purpose of ascertaining what practical impact the regulations will have.

And that thereafter, prior to the final promulgation of such regulations, a public hearing should be held at which some form of cross-examination of EPA's technical experts is permitted. What is your reaction to this suggestion?

Mr. Zener. I think these meetings take place anyhow. I don't know of any case where an industry has requested a meeting, where that request has been denied. This is one of the primary ways in which the Agency learns about the practical effect of what we are doing and we are very interested in learning the practical effect of what we are doing or what we propose to do.

As for the second part of that suggestion, as I previously stated, I don't think the formal hearing with cross-examination is worth the delay that these hearings inevitably entail. The types of technical questions that we are called upon to resolve, they don't lend themselves through—to illumination through cross-examination.

It is much more fruitful to get the technical experts in a room together talking together in a nonadversary content. When you do that, frequently you find that most of the technical questions involved are resolved. The areas of disagreement are confined very narrowly.

If you throw the thing into a courtroom setting, you get tremendous delay and you also tend to discourage the type of agreement on technical issues you would get on an informal conference basis. That was my experience in connection with the promulgation of the effluent limitation guidelines for the steam electric powerplants.

Mr. Pedersen here might comment on the experience he had in connection with the automobile suspension decision. He participated in a technical conference among the experts involved.

Mr. Pedersen. In the *International Harvester* case, Judge Leventhal required EPA to provide an opportunity for cross-examination on appropriate showing by the industry. We have had 3 automobile suspension hearings since then and the right of cross-examination has never been exercised.

In the first hearing one request was received but it was dealt with to the satisfaction of everybody by an informal off-the-record con-

ference to discuss how the Agency would analyze the data. In the last two hearings there hasn't even been a request.

Mr. TOBIAS. Do you believe that the EPA should perform NEPA type analyses prior to adopting new regulations?

Mr. ZENER. I am not quite sure what you mean. The analyses we go through in connection with our regulations does consider the cost, the control technology and the impacts of the proposal on other aspects of the environment. To that extent, I think the answer is yes. We do conduct NEPA type analyses.

Let me cite an example, in connection with the control of emissions from cement plants, a question was raised concerning the possible water pollution impacts—no, it was not cement plants. It was some other kind of plant. Anyway, a question was raised concerning the water pollution and we analyzed that impact.

That is what I would consider to be a NEPA type analysis.

Mr. TOBIAS. EPA has been criticized for not publishing clarifying amendments to its regulations in a timely manner.

Mr. ZENER. I would have to focus on a specific example.

Mr. TOBIAS. An example would be the new rainfall construction run-off regulations for powerplants. Ambiguity exists as to the area covered, but widespread agreement exists inside and outside EPA on what area actually was contemplated as being covered.

And yet, the ambiguity in the regulations themselves has never been clarified.

Mr. ZENER. I don't know enough to expound on that particular one. Generally, in almost any regulation you put out there are ambiguities. There have been some cases where we have not clarified these quickly enough. With the volume of regulation issuance that our statutes require us to engage in. I am not surprised.

I would hope we could do better. Beyond that, it is difficult to react.

Mr. TOBIAS. Under the Water Act, the Congress delegated to the EPA tremendous authority to promulgate rules and regulations implementing the statutes. Do you believe that the standards guiding agency decisionmaking in promulgating these rules and regulations have assisted the Agency in its efforts?

Mr. ZENER. That is a hard question to answer. On the whole, I think it depends on the section of the statute you are talking about. Section 304 governing effluent guidelines has on the whole been helpful. The Congress required us to consider cost and effluent reduction benefits and list the effects. It has been helpful to know these are factors we must consider.

On the other hand, within the context of standards that Congress has laid out, there is tremendous discretion in the agency to pick a particular number. I don't see how it could have been different. I get the sense that there was perhaps an attempt on the part of the Congress then to lay down specific instructions so that the agency won't have a great degree of discretion.

But I think on the whole that attempt has not worked. It really can't work. If you are talking about the pounds of a particular kind of pollutant that an industry can emit through its stack or through its discharge pipe in an hour or in a day, Congress simply can't lay down a specific instruction from which you can more or less automatically derive a specific number.

It is simply the nature of the case that the agency has to be left with a large amount of discretion. The standards that are laid down in the statute are helpful to some degree, but the amount of choice that the agency is left with is tremendous. The statute does not really give you the answer when you are trying to figure out what the standard ought to be.

I only know of one instance in which Congress has actually set the standard and that is automobile emissions in the Clean Air Act where they required a 90 percent reduction. I don't think there is any way in the world that Congress can do that for every industry that has to be covered.

All Congress can do is lay down general standards which are helpful but don't really give you the answer when you are faced with the problem of formulating a specific number that is to be applied to a specific industry.

Mr. TOBIAS. Do you think changes could be made in the Water Act that would better assist the Agency in its efforts?

Mr. ZENER. With regard to 301 and 304, for example, no. We have a problem in 307 with toxic standards because it is not clear with respect to whether cost and feasibility can be considered. That is the kind of question that Congress could address itself to. I think when you are talking about questions of degree—the relative degree of uniformity versus flexibility in a nationwide industrial standard, these are questions that have to be settled with reference to a study of the particular technology of a particular industrial category. I don't think it is practical to think that Congress can address itself to matters of this degree of specificity.

Generally the answer is no. I don't think the standards of sections 301 and 304 could be meaningfully amended.

Mr. TOBIAS. We understand that on several occasions your office has refused to consider a question of constitutional law proposed by a party in an adjudicatory hearing on the grounds that such questions are more appropriately addressed in the U.S. court of appeals.

Why has the Agency responded in this manner to questions which raise issues of constitutional law?

Mr. ZENER. I don't think there is much benefit to be gained by establishing a special procedure for the General Counsel to render opinions on questions of constitutional law.

These questions will be inevitably settled by the courts and when they are settled by the courts, I don't think the court is going to have the least interest in what the EPA General Counsel thinks about the interpretation of the 14th amendment.

I think the court will have some interest in the interpretations of our regulations because this is a matter in which the agency has some degree of expertise. We don't claim to have any degree of special expertise on interpretations of the U.S. Constitution.

Mr. TOBIAS. Don't you think you could resolve some problems short of having to go to court?

Mr. ZENER. No. After all, if it has to do with the constitutionality of the Federal Water Pollution Control Act, I personally don't think that any provisions of that act are unconstitutional. I would not take it upon myself, even if I did think so, to render an opinion as to that fact.

That is for the courts to say. As for EPA's regulations, they would not have been issued in their present form if I thought that any of their provisions were unconstitutional.

So it really would not be profitable, I think, for our office to consider contentions, of constitutional questions directed toward any of our statutes or regulations. I just think it would be a waste of time for that procedure to be gone through.

That is for the courts.

Mr. TOBIAS. Under the NPDES program exceedingly complex judgments must be made by EPA and State officials pursuant to section 316(a) and 316(b) of the Water Act. For several years EPA has been working on guidance manuals which are to govern decisionmakers in their implementation of section 316. Why has publication of these manuals been so delayed?

Mr. ZENER. Perhaps this is an example of a situation with a lack of a statutory deadline. I don't know the answer to that other than to say that these are exceedingly complex matters and their resolutions prove to be difficult.

In the meantime, I don't think that the lack of manuals under section 316 has delayed the issuance of permits which after all is the ultimate regulatory action.

Mr. TOBIAS. Permits may have been issued, but great uncertainty still exists on section 316 questions, especially as to compliance with 1977 deadlines.

Mr. ZENER. There is a certain irony in these contentions. On the one hand companies say that there ought to be less uniformity, the regional offices ought to be given more flexibility. On the other hand they complain when Washington delays in issuing a manual that would impose a degree of uniformity on the individual regional permit issuance officers.

You can't win for losing.

Mr. TOBIAS. I just want to ask you a couple of other questions about EPA implementation of its obligations under the Freedom of Information Act. The agency seems to have been dealing openly and forthrightly with all parties who have requested information, and the new regulations issued on March 6 provide for facilitation of handling of requests.

Approximately how many freedom of information requests are being received per week by EPA?

Mr. ZENER. We receive approximately 20 requests per week.

Mr. TOBIAS. Do you have any idea what the impact of these requests is on the Agency?

Is it consuming time that the employees of the Agency might better use in performing their ordinary functions?

Mr. ZENER. It is burdensome.

I can't give you exact figures on it. I know in my own office I have one lawyer who is working pretty much full time on it. In connection with specific matters, other lawyers have devoted the large chunks of their time to it. I know in connection with the *Ethyl* v. *EPA*, Ethyl gave us a massive freedom of information request that pretty much required a full-time lawyer's work for more than a year.

The question of whether this time could be more usefully spent elsewhere is largely a judgmental matter that I find difficult to call.

The values under the freedom of information are important and they are worth spending some degree of Agency time on.

I will say this: The Freedom of Information Act has been largely a device by which companies obtain discovery in rulemaking proceedings. There is a lot to be said for the existence of such a discovery device but I doubt that that was really the original intent of the act that was passed.

Mr. Tobias. Do you think Congress should remedy that situation?

Mr. Zener. I don't have any answer to that.

Mr. Tobias. On May 20, EPA issued proposed regulations on confidentiality of business information. The Agency's efforts to deal with this difficult problem area are commendable. Do you think there is anything Congress could do to ameliorate the problems your Agency has encountered in this area?

Mr. Zener. Yes, there is one area and that is this: The present Freedom of Information Act requires a response to the request for information within 10 working days, as I recall with a very limited provision for extension. This is a provision I agree with in most cases.

There is one instance where I think it presents us with an impossible situation and that is the instance in which a request is made for information which may be entitled to protection on the grounds of trade secrecy or other privilege. In this connection we don't think as a matter of basic fairness, that we ought to turn the information over unless the business firm involved has had an opportunity to present to us arguments with respect to the question of whether the information is in fact entitled to confidential treatment.

It is extremely difficult to give the business firm an adequate opportunity to present those arguments to the agency within the time deadlines currently specified in the Freedom of Information Act.

So it seems to me that there ought to be some limited provision for an extension of those statutory time deadlines in a situation where a third party is being afforded an opportunity to present arguments as to why the information that is being requested should not be revealed.

Mr. Tobias. Are there any other areas with which the EPA deals where you might make suggestions for legislative change that would increase the efficiency or operations of your agency?

Mr. Zener. That is a pretty broad question.

Mr. Tobias. Would you like to submit something for the record?

Mr. Zener. We have a few requests for legislative relief pending on the Hill. I conceive my role to address myself only to procedural matters. I can't think of any. These are mostly the subject of pending legislation requests. You caught me unawares with that question.

Senator Abourezk. Thank you very much for your appearance here today.

[The prepared statement of Mr. Zener follows:]

Prepared Statement of Robert V. Zener

Mr. Chairman and Members of the Subcommittee: I am pleased to be here today to testify on the administrative procedures EPA uses to implement our regulatory programs. I will be brief in my prepared statement so as to leave as much time for your questions as possible.

EPA is basically a rule-making regulatory agency. Our three major areas of responsibility are air pollution control, water pollution control, and control of

pesticides. We also have regulatory authority with regard to noise control, the protection of drinking water, and the control of radiation hazards.

Only for pesticides does the statute give a central role to formal hearings before an administrative law judge. For our other regulatory authorities, our procedures are patterned on rule-making under the Administrative Procedure Act. In general, this Act requires any rule which the Agency is thinking of adopting to be issued in proposed form. Public comments are invited, and when the final rule is issued, the Agency must explain why it did or did not accept the major points those comments raised.

We believe these procedures have worked well. If formal, court-room type hearings had been required, EPA no doubt would have been severely hampered in putting the air and water pollution control statutes, most recently enacted by the Congress in 1970 and 1972, into effect.

Although these procedures have worked well, we do not believe they are perfect. The evolution of our rule-making practices over the past five years has been steadily toward greater procedural formality. For example, we now provide much more complete and earlier disclosure of what we plan to do and why we plan to do it. We aim at full disclosure at the time a rule is proposed.

This more open approach to rule-making was largely triggered by Judge Leventhal's opinions in the *International Harvester and Portland Cement* cases. In those decisions, the court required EPA to let the world know in full at the time it proposed an action the facts on which the proposal was based and how those facts had been analyzed. Today, we try to follow these principles in all our rule-making.

Such disclosure tells the public and industry the basis for the Agency's case and allows all parties time for review and analysis and an opportunity to point out any weak points. The *Portland Cement* opinion makes clear that a rule should not be upheld if the Agency does not satisfactorily address the issues raised in public comments received by the Agency on the rule.

Often, this approach alone has been enough to fully air the issues. That was true, for example, in the *Portland Cement* case itself, after the court had sent it back to us. Our response to the remand, which was developed through these procedures, has just been upheld in all respects by the D.C. Circuit.

Sometimes, however, further probing of the issues may be necessary. There are many ways this can be done. For example, informal conferences with the affected parties can be held, either on or off the record, or legislative-type hearings can be conducted, or interrogatories exchanged. Any one of these can bring clarity to disputed matters without the cost in time and money for formal cross-examination.

I believe Professor Williams of the University of Colorado has appeared before the Subcommittee. He has just finished a paper which contains a case study of EPA. After reading it, I believe he gives us pretty high marks for our use of new devices to facilitate comment on our rules. I believe he also agrees with us that cross-examination in rulemaking has very few advantages to offset its drawbacks.

What I have said so far reflects the law and practice at present. But this is a changing field. The legal system hasn't adjusted completely to the tremendous growth in rule-making which the legislation of the last few years has triggered.

In general, I believe the trend is still toward greater use of some formal procedures, and to even stricter requirements that the Agency put all its cards on the table. At the same time, I believe the courts will try to make sure that any new procedures are less open to abuse by regulated industries and their lawyers than some procedures used in the past.

In particular, I believe the next centers of attention in this regard will be the nature of the record in informal rule-making and the relationship of the Freedom of Information Act to the Agency's obligation to make full disclosure.

However, I'd rather not speculate too much on the future. The case law has been developing so quickly and so satisfactorily, in the past few years, that I think the best thing to do for the present is to just let it go on developing.

I'd be pleased to answer any questions you may have. Thank you.

Senator Abourezk. The next group of witnesses is a panel consisting of Turner Smith, Richard Powell, Henry Nickel, and Richard Jones. Will that panel come forward?

TESTIMONY OF A PANEL COMPOSED OF TURNER T. SMITH, MEMBER OF THE LAW FIRM OF HUNTON, WILLIAMS, GAY, AND GIBSON; RICHARD POWELL, ATTORNEY FOR ISHAM, LINCOLN, AND BEALE; HENRY V. NICKEL, MEMBER OF THE LAW FIRM OF LEBOEUF, LAMB, LEIBY, AND MACRAE; AND RICHARD JONES, ASSOCIATE GENERAL COUNSEL FOR THE CAROLINA POWER AND LIGHT CO.

Senator ABOUREZK. Mr. Smith, I understand you are the group leader. Please proceed. Do you have separate statements?

Mr. SMITH. We do all have separate statements. I think Mr. Nickel could lead off.

Senator ABOUREZK. Wait until the reporter has the names of everybody here.

Mr. SMITH. Yes, Senator.

Senator ABOUREZK. First of all, I would like to welcome you to the Senate subcommittee hearings and thank you for your appearance here today.

Mr. NICKEL. I appreciate the opportunity to testify here today. As counsel to electric utilities companies regulated by EPA, I have participated in rulemakings and adjudications under both the Clean Air Amendments of 1970 and the Federal Water Pollution Control Act Amendments of 1972.

As you know, both statutes require EPA and the States to make extremely complex technological, social, and economic judgments in general rulemaking proceedings.

No matter how fair rulemaking procedures may be however, public confidence in the final product will be undermined if the Agency does not have sufficient time to formulate its proposals and the public is not provided a reasonable time within which to comment. EPA regulations under both acts are subject to criticism in this regard. The fault, however, is not with EPA but with Congress.

Under the Air Act, EPA and the States were given less then 18 months to develop the complex and comprehensive regulatory program envisaged by Congress. The Water Act imposed even more stringent deadlines on EPA rulemaking. It has been my experience that in the case of many of the EPA rulemakings, the statutory deadlines have not allowed industry time to respond fully to proposed regulations.

I also believe that the deadlines in these acts have frustrated the congressional desire that EPA rulemaking result in precise regulatory requirements that may be reasonably applied to individual sources of pollution.

I am not, of course. advocating eliminating statutory deadlines. Deadlines are necessary to avoid the unreasonable delay that characterized implementation of prior air and water legislation.

Parkinson's law is not unknown to regulatory agencies. However, I believe Congress has an obligation in setting statutory deadlines to assess realistically the time required to staff an agency for new assignments, the time needed to acquire necessary information, and the time necessary to allow the public to participate meaningfully in agency decisionmaking. I am afraid this was not done in the case of the Water and Air Acts, and the regulatory programs suffered as a result.

As I have mentioned, the Air and Water Acts direct the establishment of precise pollution control requirements through the technique

of general rulemaking proceedings. Although the effective use of this technique was frustrated by the hurried nature of the rulemaking, I question whether EPA would ever be able to establish by regulation requirements that could be applied with fairness to each facility subject to the regulation.

The variables are too great.

In the case of the Water Act, EPA established variance procedures in its guidelines for 1977 effluent limitations but did not provide similar procedures in its 1983 guidelines. In the case of both acts, EPA has not provided a mechanism whereby new source standards may be varied in appropriate cases.

In my opinion these omissions are not justified. Fairness requires that, at a minimum, EPA allow interested parties to demonstrate that application of a new sources standard or a 1983 effluent guideline to a particular facility is not consistent with the act.

If unique facts and circumstances—not considered when the general regulation was adopted—dictate a different requirement, EPA should establish it for the particular facility.

Another area deserving attention is the influence judicial decisions have had on EPA regulatory program. Under both the Clean Air and Water Acts, interested members of the public may file citizens' suits in District court to require the Administrator to perform a nondiscretionary duty.

In addition the administrator's rulemaking orders are subject to judicial review in the U.S. court of appeals. As a result of suits instituted by environmental and industrial groups, the courts have decided far-reaching questions of statutory interpretation. In certain cases EPA has been directed to conduct extensive rulemaking to set requirements for previously unregulated activities.

Generally only those who challenge agency action are involved in litigation. Others whose rights might be significantly affected by the outcome of litigation cannot participate for the simple reason that they lack actual knowledge that a suit has been instituted.

This situation should be remedied.

Accordingly the opportunity for broad participation by the public in the courts may be of equal importance to such participation before the agency. This is particularly true since after a judicial decision is rendered, there is no opportunity to challenge the result except to relitigate the issue.

Broader participation in litigation would assure that all relevant viewpoints are considered by the courts before interpreting the complex and comprehensive acts administered by EPA. Future litigation might be avoided if all interests are represented in the initial legislation.

Thus I believe that consideration should be given to establishing by statute or regulation a procedure for early public notice of judicial review and citizens' suits. Such notice would allow those whose interests would be affected by the litigation to intervene or file amicus briefs, as appropriate.

I would like to conclude my remarks with a few observations about the Water Act discharge permit program under which the requirements detailed in EPA promulgated regulations are applied to individual facilities.

EPA regulations establish procedures for adjudicatory hearings on any permit issued by the region. Under these regulations, initial decisions are rendered by the EPA regional administrator, and questions of law are decided by the General Counsel.

The presiding officer at such a hearing, who is an administrative law judge, is merely a fact gatherer.

I am concerned that the practice calling for initial decision by the regional administrator may prove to be unfair. First the procedure violates the principle that he who hears must decide. Second, the regional administrator may be called upon to decide issues challenging policies that he directed his staff to implement. Third, because of limited manpower, I believe there is a danger that the Regional Administrator will look to the Enforcement Division of the region—a party to the adjudicatory hearing and the defender of the contested permit terms—for assistance in preparing his initial decision.

I see no alternative to this practice, however, given the few administrative law judges assigned to the Agency. Presently EPA has three administrative law judges handling several hundred permit cases. If the number of judges can be increased, I believe it would be desirable for EPA to change its regulations to provide that presiding officers at adjudicatory hearings render "initial decisions" or at least "recommended decisions" for the regional administrator.

A final area of concern to me was addressed in questions to Mr. Zener. Several times the General Counsel has refused to consider a question of constitutional law posed by a party to an adjudicatory hearing on the grounds that such questions are "more appropriately" addressed in the U.S. court of appeals.

First, I believe this response encourages unnecessary litigation. Second, it is an abdication of the Agency's responsibility to assure that its activities are conducted in a manner which conforms to constitutional requirements. Finally, where such claims relate to the procedures followed by the Agency, there is clear judicial authority for the Agency to modify its procedures in the interests of justice.

Thank you, Mr. Chairman.

Senator Abourezk. Thank you. Please present all of the opening statements before we commence questioning you.

Mr. Smith. Fine. Mr. Powell?

Mr. Powell. Thank you. In my written statement I make three recommendations. One, the Environmental Protection Agency ought to be required to make the NEPA-type analysis before they do anything. If I understood Mr. Zener's answer to a question, he indicated the Agency does that. They have not done any type of NEPA analysis, and that issue has been litigated in three or four courts of appeals.

Essentially, their position is that in setting standards, they could not consider the cost or technology questions. However, in setting the standards, they have been directed to set those standards with an adequate degree or an adequate margin of protection. It seems to me impossible to define what is an adequate margin of protection without considering questions of cost and technology.

If NEPA should be applied anywhere, it should be applied there. Once the standards are set by the Federal EPA, the States have small leeway. A cost-benefit analysis done after the air quality standards have been set is too late.

Another point made in the statement concerns the delineation between Federal and State roles. My third point is to suggest a restructuring of EPA, and that is the point I would like to concentrate on.

It seems to me that the functions presently assigned to EPA cannot logically or rationally be handled by one single individual as, for example, the Clean Air Act directs. Under that act, the Agency has the responsibility for doing all research and development work which are the information bases for setting the standards.

At the same time, the agency is required to be a vigorous enforcer. There is an inevitable conflict between what regulatory action can be taken on the basis of the given data base.

It is left to the administrator and the administrator alone to resolve that question. I think it would be impossible to find another field or agency where the broad scope of power—it is impossible to find this in another Federal agency. This could be changed by adopting the structure like in Illinois where there is an independent rulemaking body. In Illinois, there is a body called the pollution control board which has the authority both to set substantive regulations and has the judicial function of hearing variance cases.

There is an independent environmental protection agency and the independent research institute. Either the agency or the institute can propose regulations to the board. But the board has to conduct a public hearing. Contrary to Mr. Zener's view, my own view is that public hearings are not only helpful but essential.

It is a practice consistently employed in Illinois for 4 years. It does not lead to prolonged regulatory proceedings, and it is important to cross-examine technical witnesses. It has been stated by the board itself which has conducted these hearings that it benefits by a public hearing where counsel can cross-examine witnesses.

When you are dealing with opposing and difficult technical questions, it is helpful for the decisionmaker to have a technical expert to appear before him to be cross-examined before he forms a judgment as to which view is right.

On most of these technical questions, there are more than—it is not uncommon to find an expert who is willing to testify on both sides of the question.

Another restructuring, if the Congress would not be willing to adopt this procedure, would be to make the research and development function of the Agency into a separate independent agency. I think that that is the only way that the research and information data base upon which environmental regulations must be rationalized can be presented fully, fairly, and adequately.

When the person who has the rulemaking authority has control over the research and development work, there must be a temptation to either color or suppress information to support the view of the regulations that are adopted.

I think that today the dispute that is presently going on between—the dispute that is current on the question of sulfates provides a clear picture of the temptation for a regulatory agency to stretch what the data base shows. The Environmental Protection Agency appears to be taking the position that its concern over the sulfate question

means the States have to be cautious if not prohibited from relaxing sulfur dioxide emissions.

The EPA on the one hand is saying that clearly sulfur dioxides alone are not the health issue even though that is the pollutant for which a standard exists. Although we have not set a standard for sulfates, that is the emission we ought to be concerned about.

More recently, they have obtained information that nitrates are the problem. The EPA said in Illinois that Illinois has to in certain areas of the State not relax sulfur emission standards because of their concern over the sulfate issue for which there is no adequate research and development data.

I think there inherently is a conflict when one single person has the authority to set the rules, to enforce the rules, and to control the research and development which is the data base. I think that at a minimum, the research and development work now assigned to an agency ought to be put into an independent agency.

Preferably, I would like to see an independent rulemaking body to which the Agency would have to propose rules and have that body conduct a public hearing in which parties can cross-examine witnesses before a rule can be adopted. I think that there is probably no area in a Federal regulation which has impacted the public more than the environmental field today.

I think that any effort that can be made to justify a more rational process is worth it. Thank you very much.

Senator Abourezk. Thank you very much.

Mr. Smith. This committee's inquiry is an important one. As Justice Jackson has said: "The rise of administrative bodies probably has been the most significant legal trend of the last half-century . . . " That trend has continued apace.

Recent environmental laws are part of a new wave of administrative control breaking over the private sector. They raise large and fundamental issues. The economic stakes, for example, are huge. EPA's water pollution regulations under the Federal Water Pollution Control Act will, for the electric utility industry alone, cost about $6.6 billion by 1983, even by EPA's estimates. Implementation of EPA's current policy as to one air pollutant, SO_2, will impose capital costs on that same industry of at least $6.5 billion by 1980 yielding a total of $13.1 billion at stake for these phases of regulation in this industry alone. Yet this industry is already wracked by acute financial crisis because of prolonged inflation.

Not only are the economic stakes high, many of the new environmental controls raise fundamental longrun questions of social impact. Air and water quality ambient standards, for example, have direct land use implications, since new industrial, residential, or automotive pollution sources will be effectively zoned out of many areas when those ambient limits are approached, as they already have been in many cases.

These land use constraints are, however, only a belated legal articulation of more fundamental natural limits on human agglomeration. And as such, they have the potential for radically restructuring the geography of both our urban and our rural areas.

Delegations of lawmaking power with such awesome scope and consequences, while frequently necessary to cope with the complexity

of modern society, are legitimized only through careful control by Congress and the courts. Congressional oversight is one such tool and contributes to a vital tradition of continuing reassessment of our administrative agencies.

In the interests of time, I will leave to my prepared statement a full development of the specific issues I have raised with regard to EPA's implementation of the Air and Water Acts. I will comment now on several of those issues.

I agree with other members of this panel that EPA rulemaking processes are not as accurate and responsive as they need to be. The use of *International Harvester* rights depends critically upon active, intelligent, and timely participation by industry and by the public in developing the rulemaking record and thrashing out particular issues.

While this participation is sometimes forthcoming when the issues are quite significant, it is frequently not forthcoming either because the industry is unable, in the time available, to gather itself together and attack a problem with its joint resources, or, alternatively, because those resources, whether jointly or severally, are simply deployed, inadequate given the pace and broad extent of present regulatory activity. As a result, many significant regulatory problems are not being addressed by the regulated industries in the depth they merit.

I suggest a slightly different solution to this problem than that suggested by Mr. Powell—the establishment of a formal, independent, blue ribbon group to provide written, public comment on the technical premises involved in each EPA proposed rulemaking. This would amount to institutionalizing an opinion from a body like the National Science Foundation in the rulemaking process, insuring that an external scientific judgment as brought to bear, regardless of whether industry participates in the rulemaking in question. I think you can see, from the extent to which we are dwelling on this problem of technical and scientific accuracy in the rulemaking process, that it is one that bothers all of us.

The second issue that I would like to address briefly is the question whether Congress has provided adequate statutory standards in its environmental legislation to guide agency discretion.

I think Mr. Zener correctly indicated that the latitude given EPA on these matters under the existing legislation is really immense. But he felt that Congress probably could not have been much more precise and particulative in how it wanted standards set. I disagree with that judgment. I believe, on the one hand, that it is unwise for Congress to attempt to set new numerical limitations in the statutes. One the other hand, what Congress has done in sections 301 and 304 of the Water Act—the sections setting the basic technological limits—is to list a number of relevant factors to be considered. Congress could have gone further, in my judgment, and attempted some weighting of those relevant factors or indicated to the agency what relative weight they should have been given. In addition, the nature and application of the relevant factors could have been more precisely defined. Simply indicating that "cost" is to be taken into account leaves open many questions of a generic nature that could easily have been resolved in the Congress. For example, did Congress mean that, as to any given

regulation, no single processing or electric generative unit is to be made to bear such a cost that its operation becomes unprofitable? Is this determination rather to be made as to a whole plant or production facility? Is the question really whether the company in question, the entrepreneurial unit, can bear the cost? Or must EPA simply find that the entire industry can bear the cost, even though some of the companies in it will go under?

And what definition of profitability did Congress intend? How does any such definition apply in a regulated industry?

I think that these questions could profitably have been addressed by the Congress. There are others as well. This is just one area in which the Agency's discretion could have been limited to advantage and a great deal of confusion eliminated as well. While it may sound from my comments now and those in my prepared testimony that I do not believe EPA capable of any wise and useful action, that is not the case. As I noted in my testimony, the Agency is working very hard and, on the whole, honestly to carry out very difficult congressional mandates under almost impossible congressional deadlines.

Despite this, however, several things are clear. First, EPA can be wrong on occasion. Second, EPA's errors could be reduced if it would:

(a) Set rules where rules are needed, apply those rules flexibly once set, and abjure "under-the-table" policymaking procedures.

(b) Treat technological facts, or the lack of them, as objectively as possible.

(c) Weigh the costs and benefits of its proposed actions within the context of the substantive mandate of its organic legislation.

(d) Articulate publicly and carefully the bases for its decisions, and,

(e) Insure that its regional officials conform to those decisions.

Third, the Congress has not given EPA the sort of careful and precise, but efficient, statutory guidance that EPA and the public have a right to expect where such fundamentally important social issues are committed to the administrative process for solution.

Fourth, the Congress has compounded the problem by imposing rigid, unrealistic deadlines on EPA and by requiring immediate challenge and litigation of the administrative output.

Finally I must note that Congress and the States have been passing environmental laws with great abandon—Federal and State NEPA's, laws affecting air pollution, water pollution, pesticides, radiation, and noise; laws affecting and relating to coastal zone management, land use, and energy policy. These laws have proliferated into such a crazy quilt of overlapping and conflicting jurisdictions and requirements that the private sector is beginning to feel like Gulliver in the hands of the Lilliputians.

I do not argue that tough, fair minded environmental controls are not proper—they are long overdue. What is required now, however, is a statesmanlike effort by the Congress and the State legislatures to untangle the present mess and recodify, with careful craftsmanship, environmental control requirements into clear, simple jurisdictions and requirements. This more than anything else will foster faith in the efficacy of the administrative process for solving environmental problems.

Until Congress and the State legislatures get their own houses in order, however, it is very difficult, if not impossible for anyone downstream of them in the lawmaking and law-applying process to do so, to the severe detriment of the public interest.

Thank you, sir.

Senator ABOUREZK. The Agency often has been accused of taking the position that it must protect the environment at any cost notwithstanding language in many statutes that requires EPA consideration of technological and economic factors in its decisionmaking.

In your dealings with the EPA, do you believe the Agency has ever exceeded its statutory authority or ignored its statutory mandate in this manner?

Mr. JONES. I think, yes, at the level at which permits are issued, you are more likely to run into this than at the rulemaking, although even at the level of rulemaking, you are dealing with an attitudinal thing to a large extent that can color the risks being taken in writing the regulations.

I think frequently the risks are taken on the side of assuming that a technology is available that is not. This exceeds statutory authority, I think, whenever that is done. But specifically at the level of issuing the NPDES permits, I have had some experience at the regional level with attempts to use State water quality standards as a means of leading you to what really is a more stringent standard than the national effluent guidelines provide.

Under the Federal Water Pollution Control Act there are two types of standards. There are technologically based standards mandated by the 1972 amendments. Then there is a backup control using the preexisting water control standards.

We saw permits being issued which imposed limitations on the discharge of chlorine which went into—below the level permitted by the national technologically based guidelines. There was no real attempt to explain the authority for this or to develop any sort of a record showing that within the language of State water quality standards there was authority for this more stringent standard.

It was just a feeling that you can get chlorine discharges down to a level lower than the national standards provide, if you can, then you ought to do it.

Mr. SMITH. I have two examples that may prove useful, the first more minor than the second. An example in the rulemaking context occurred when EPA originally established regulations for rainfall runoff during construction from powerplants. In our judgment those regulations exceeded their authority because a good deal of such rainfall runoff is from nonpoint sources, not from point sources. EPA has now cured that problem, at least formally, by inserting in their regulations the words "point source" to modify runoff. I think, however, that there will still be a great deal of hassle as to what is and what is not a point source.

A second somewhat similar example is their present policy, largely informal, of refusing to reduce present sulfur oxide emission limitations, even where ambient standards would still be met. Mr. Powell addressed this issue. The way the Air Act is set up, EPA should establish ambient air quality standards for sulphates, if it has enough

information to do so. If it fails to do so, then the only measure for the adequacy of the emission limitations in State implementation plans ought to be whether they are necessary to meet the existing ambient air quality standards. Sulphate controls is an area where EPA has fixed on a policy which they believe to be right but for which they have no clear statutory authority.

Mr. Tobias. Most of you have registered dissatisfaction with EPA's handling of technical data in the decisionmaking process. We heard from FDA on Monday that the Agency uses advisory committees composed of independent experts not dissimilar to the blue ribbon commissions Mr. Smith mentioned.

Could we have the further thoughts of all of you on this problem?

Mr. Nickel. I would like to comment on that specifically because I think this points out one of the problems which was created by the statutory deadlines. Section 515 of the Water Act established an Effluent Standard and Water Quality Advisory Committee that was to review and advise the Administrator on proposals for effluent limitations and other standards under the act.

The committee was formed but its proceedings were held under impossible deadlines. I know from talking to the chairman of the committee that they did not have a staff, even typists, for a number of months.

The end result was that the committee could make very little contribution to the Agency's development of effluent guidelines. It was too much coming too fast without an adequate backup staff. They had very fine people on that committee but there just was not time to do the job.

Thus, I believe that this Advisory Committee could have provided the type of mechanism that we are talking about here but it simply could not make a meaningful contribution within the time period allowed.

Mr. Tobias. Do you think such committees could be feasible and workable? Is it just a matter of staffing?

Mr. Nickel. I think they can add a great deal.

Mr. Powell. I think that the use of such committees would be better than the present situation but only if the EPA were required to consult the committee prior to the adoption of any regulation.

However, I think an advisory committee or a review panel is an inadequate substitute for an independent rulemaking body before whom the agency, the public and affected industries can appear and present their views. I think the public hearing process is absolutely critical.

I do not think that putting technical experts into a room resolves anything because the technical experts, to my knowledge, are not the ones who ultimately decide the policy questions. It is the policymaker, the person who actually decides the bottomline, who ought to hear the experts and ought to hear those experts cross-examined by other experts or ought to hear the opposing experts' points of view.

This is a procedure which has been used in Illinois. It has not resulted in unduly long regulatory proceedings. It is required prior to the adoption of any substantive regulation in the State. The pollution control board itself has said that it has benefited in its decisionmaking process.

To give you an example, I don't see how anybody, any expert or lawyer or whoever the decisionmaker is could possibly have resolved the question of whether flue gas scrubbers are or are not a viable technology without cross-examining the opposing points of view.

You cannot resolve that question by reading the EPA position papers EPA witnesses have testified on this issue in Illinois and stated views on at least four occasions within a period of a year and a half.

The testimony ranged from the first witness who predicted that sulfur removal technology would be available within 2 years. A little later, it was stated that it was not proven and one witness cited technology which the industry has since abandoned. On the third occasion, they indicated that the technology was proven largely on the basis of the experience with a few so-called wet, throwaway scrubbers.

On another occasion it was stated that the wet scrubbers were a waste of resources and had unsatisfactory reliability experiences. The EPA finally stated the facts as they are but only after emission limits had already been adopted by the States and costs had already been imposed on the industry.

Mr. Zener indicated earlier that one of the ways the EPA has evaluated offsetting environmental concerns was in their evaluation of wet desulfurization systems and their possible effects on water pollution. It has only been recently, however that the EPA has even acknowledged that a water pollution problem existed.

They have repeatedly testified earlier that there was no such water problem. I think these problems can be resolved only if the decisionmaker has the benefit of seeing the persons who have opposing points of view and have them cross-examined.

Mr. Smith. I was going to add this to what Henry Nickel has said. I think there are already a lot of advisory committees lurking in the shadows of the EPA rulemaking process. What is required, at a minimum, is that Congress give them a much higher profile in the decisionmaking process. For example, they should be required to report in writing before EPA takes action and EPA should then be required to explain, in its statement of the basis for its rule, any deviation by it from the technical judgments made by that committee. Thus, the committee's judgments would not bind the EPA, but EPA would be required to pay attention to them and do so publicly, articulating the bases on which it disagrees. As a minimum, that is required to make the existing committees work. I reserve judgment about Mr. Powell's proposal. It is an interesting one that ought to be considered.

Mr. Powell. I would like to add just one further point. Without something along the line that this panel has been suggesting, it is virtually impossible for the person affected by EPA regulations to obtain meaningful court review. Without having a recorded public hearing, it is impossible for anyone to have a court review of regulations of EPA.

The court almost always has to assume that the EPA is right and meaningful court appeal is lost.

Mr. Tobias. EPA often must interact and cooperate with other Federal agencies, such as the Nuclear Regulatory Commission, in administering its programs. In your dealings with EPA and such Federal agencies, how would you rate EPA's ability to interact effectively with these other Federal agencies?

Mr. JONES. There has been very little evidence of EPA's making any deliberate attempt to ease the burden created by multiple agency decisionmaking. A case in point is the interaction between EPA and the Nuclear Regulatory Commission in conducting reviews of the impact of nonradiological effluent discharge from plants.

Section 511(c)(2) of the Federal Water Pollution Act of 1972 took away the authority Federal agencies previously had under the National Environmental Policy Act to establish conditions designed to protect water quality. However, at this point we are still fighting with NRC about whether or not they can include water quality type limitations as conditions of their licenses which are different from those which EPA is requiring us to comply with.

We are getting caught in a trap. At this point it does not seem that EPA has done anything to straighten the problem out in terms of telling NRC "Look here, Congress told us to do this. You stay out of it."

We are still having to try to steer a line between the two agencies and fend for ourselves. It is not easy.

Mr. NICKEL. Nuclear powerplants are constructed under a very long leadtime. You need a construction permit a number of years before you actually operate that plant. Under the Water Act, there is a requirement for State "certification" of compliance with Water Act requirements. Such certification is a prerequisite to the issuance of an NRC construction permit. Also, NRC regulations indicate that NRC will not make water quality determinations once there are affirmative determinations by EPA or the States of compliance with water requirements.

I have seen a great reluctance on the part of both EPA and the States to meet these issues at an early stage. I think it is very important that they attempt to meet these issues early because you must receive an authorization from NRC before construction begins, and important design and construction decisions must be made before that time.

EPA is considering procedures for "preliminary determinations" on certain Water Act requirements. I would hope, however, that EPA and the States go further and establish some procedure for final resolution of water quality requirements before construction begins. This would allow plants to be appropriately designed and help to assure that construction proceed without delay.

Mr. TOBIAS. The provisions for judicial review set out in the Air and Water Acts are rather complex. Have such provisions caused difficulty for you in representing your clients?

Mr. SMITH. I think it is fair to say they have in at least two regards, one of which I think is probably transitory. First, there are a number of specific EPA actions under both the Air and the Water Acts for which judicial review lies in the courts of appeals directly. These appeals do not go through the district courts at all. The sections providing for these appeals are badly drafted, and it is frequently difficult to tell whether you should be in district court or in the courts of appeals. The typical response has been to file in both courts and to litigate the jurisdictional issue—a needless waste of everyone's resources.

This problem is transitory since we will begin to build up case law on which issues properly go to the circuit court and which do not.

But the lack of specificity has created a good deal of unnecessary litigation, just on the question of jurisdiction.

Second, the procedures for judicial review in the circuit court require immediate judicial review on pain of being foreclosed from collaterally attacking the action or regulation at a latter date. I have no way of measuring, but in my judgment, this requirement has spawned a lot of premature litigation, particularly in areas such as EPA's effluent limitation guidelines. Under the Air Act, industry did not wake up early enough to the fact that it had to go to court within 30 days after EPA had taken some action. Under the Water Act, however, people finally got the word, and there has been tremendous proliferation of lawsuits on EPA's promulgation of effluent limitations guidelines. Many of them are promptly settled out, but they do impose a tremendous burden on the EPA staff and on the courts.

I suppose that some mechanism for flushing out problems with the regulations fairly promptly is warranted. But there are some cases where people simply do not realize early enough, for a number of different types of reasons, that a regulation will affect them. At present, anyone who didn't know to participate at the rulemaking stage cannot recover later.

Mr. Powell. I agree with Mr. Smith. There is another point where to the extent that Federal law imposes upon the States an obligation to adopt the regulation which becomes enforceable as a State law, and when it is approved by the Federal people, it becomes enforceable as a Federal law.

You are sitting there with the air regulations, and the State adopts it and it becomes State law. When the Federal Government adopts it, it becomes Federal law.

Therefore, if you want to challenge those rules, you have to appeal now in both the State and Federal courts on essentially the same issue.

When Illinois adopted emission limits, we filed an appeal from that in early 1972 which is still pending in the State courts. When the Federal Government approved the State implementation plan, we were forced to appeal that in the court of appeals because otherwise it could have been enforced as a matter of Federal law even if we are successful in State courts.

I think that some procedure ought to be adopted where you don't have to litigate identical issues.

Mr. Smith. I think Mr. Powell is quite right. He has put his finger on a generic problem. I think Mr. Zener was right this morning in saying that we are evolving a new sort of partnership between the Federal and State governments in lawmaking. In my judgment, however, inadequate thought was given to meshing the new legislation with old legislation. For example, do NEPA or the APA apply to State action under delegation provisions?

Careful thought was not given to many other anomalies created by this new Federal-State relationship. For example, what is the appropriate forum for judicial review where States take delegated action, and the Federal Government reviews it? If this Federal-State framework is used in future legislation, some careful analytical thought ought to be given to the substantive and procedural problems it spawns.

Mr. NICKEL. I think that there is an incredible danger associated with the Water Act judicial review provisions, in that the act may produce more litigation than anything we have seen in the past. This arises out of the provisions governing judicial review of discharge permits issued by EPA.

EPA is issuing thousands of these discharge permits. If a permittee knows that it is impossible to comply with any of the terms of a final permit issued by EPA—no matter how minor—it is essential that the permittee file a petition for review in the U.S. court of appeals. The Water Act precludes a challenge to permit terms in enforcement proceedings.

In the case of the Air Act, certain courts—in cases involving general rulemaking decisions and procedures—have held that individual claims of impossibility could be considered at the enforcement stage despite a prohibition similar to the one in the Water Act. I do not see that opportunity being afforded in the case of the Water Act permit program, however, because you have a right to a full hearing before the agency on the terms and conditions of the permit. As a result I think we could find our courts flooded in the next year and a half with hundreds and hundreds of petitions for review involving very, very minor issues.

Mr. TOBIAS. Could that situation be remedied by legislation?

Mr. NICKEL. I think it could be remedied by legislation. I think that thought should be given to the degree to which individual claims of impossibility or other factors should be relevant in individual enforcement proceedings. As I mentioned in my statement, these claims should also be relevant at the time that requirements are applied to individuals in the permit cases.

Mr. JONES. I think it could be remedied very easily because the problem stems from language in the Air and Water Acts to the effect that any actions which could have been appealed within 30 days in the Air Act and the 90 days in the Water Act, any matter which could have been appealed during that time period which was not cannot be raised as a defense in an enforcement proceeding.

If that language was stricken from the acts, it would go a long way toward solving this problem. The situation is pretty rough right now because you have to, at the rulemaking, be able to anticipate all of the ways that that regulation could affect you at the time of its actual implementation to each of your facilities.

This, in a sense, involves anticipating how it is going to be interpreted by the agency.

The decision you have to make is whether to take your chances or whether to go to the expense of litigation in the court of appeals. Some of these issues are important but not crucial.

So you end up really, I think, more times than not, complying and taking your chances. In a sense, you have been pressured out of your rights.

Mr. SMITH. I think this is particularly true where there is an ambiguous permit term. If the term is interpreted one way, it is objectionable and possibly illegal. But if you interpret it another way it is OK. You cannot get any assurance, at the outset, how it will be interpreted. There is no real reason to litigate the question of validity if,

as the permit is later interpreted by EPA, it never arises. Yet in many cases you are forced to seek judicial review now for fear of forfeiting your right to challenge the term if the "wrong" interpretation prevails.

Senator ABOUREZK. We may have some additional questions to ask you to which we ask that you respond in writing. Your contribution has been very valuable here this morning. I am going to recess the hearings now until 2 o'clock this afternoon. I want to thank all of you very much for your appearance and your testimony.

[The prepared statements of Mr. Nickel, Mr. Powell, Mr. Jones, and Mr. Smith follow:]

PREPARED STATEMENT OF HENRY V. NICKEL

My name is Henry P. Nickel. I am a member of the law firm of LeBoeuf, Lamb, Leiby & MacRae and practice here in Washington. I appreciate the invitation to testify today on the regulatory programs administered by the Environmental Protection Agency.

As counsel to electric utility companies regulated by EPA, I have participated in EPA rulemakings and adjudications under both the Clean Air Amendments of 1970 and the Federal Water Pollution Control Act Amendments of 1972. My remarks today will be directed to the procedures employed by EPA under the Air and Water Acts in formulating regulations and in applying those regulations to individual industrial facilities.

As you know, both statutes require EPA and the States to make extremely complex technological, social and economic judgments in general rulemaking proceedings.

In the case of the Clean Air Act, EPA was to guide and supervise the States in developing comprehensive pollution control programs. Those programs, known as implementation plans, were to bring about compliance with EPA promulgated ambient air quality standards through the establishment of specific controls on each source of pollution that contributed to violation of ambient standards. State plans were subject to EPA approval and, if the plan did not meet federal requirements, EPA was directed to promulgate regulations establishing a plan, or portion thereof, for the State.

In the case of the Water Act, existing industrial facilities must meet specific effluent limitations reflecting the "best practicable control technology" by July 1, 1977. More stringent limitations—"best available technology"—must be achieved by July 1, 1983. These limitations, in turn, are derived from EPA promulgated guidelines for classes and categories of industrial facilities.

Both the Air and Water Acts require EPA to promulgate industry-wide technologically-based standards which establish precise controls on discharges from new facilities.

Given the enormity of the regulatory assignment under these Acts, I believe that EPA's rulemaking performance from the perspective of procedures is entitled to more praise than criticism.

In rulemaking under both Acts, the agency has, as a general practice, solicited public comment before taking action. In certain instances, the agency has held public hearings. Most important, the agency has, in my view, genuinely attempted to reflect, or at least respond to, the comments received by diverse interests in formulating its final regulations.

No matter how fair rulemaking procedures may be, however, public confidence in the final product will be undermined if the agency does not have sufficient time to formulate its proposals and the public is not provided a reasonable time within which to comment. EPA regulations under both Acts are subject to criticism in this regard. The fault, however, is not with EPA but with Congress.

Under the Air Act, EPA and the States were given less than 18 months to develop the complex and comprehensive regulatory program envisaged by Congress. The Water Act imposed even more stringent deadlines on EPA rulemaking. It has been my experience that, in the case of many of the EPA rulemakings, the statutory deadlines have not allowed industry time to respond fully to proposed regulations. I also believe that the deadlines in these Acts have frustrated the Congressional desire that EPA rulemaking result in precise regulatory requirements that may be reasonably applied to individual sources of pollution.

I am not, of course, advocating eliminating statutory deadlines. Deadlines are necessary to avoid the unreasonable delay that characterized implementation of

prior air and water legislation. Parkinson's law is not unknown to regulatory agencies. However, I believe Congress has an obligation in setting statutory deadlines to assess realistically the time required to staff an agency for new assignments, the time needed to acquire necessary information, and the time necessary to allow the public to participate meaningfully in agency decisionmaking. I am afraid this was not done in the case of the Water and Air Acts, and the regulatory programs suffered as a result.

As I have mentioned, the Air and Water Acts direct the establishment of precise pollution control requirements through the technique of general rulemaking proceedings. Although the effective use of this technique was frustrated by the hurried nature of the rulemaking, I question whether EPA would ever be able to establish by regulation requirements that could be applied with fairness to each facility subject to the regulation. The variables are too great. The courts have long recognized that whenever an agency regulates by general rule it should provide an escape valve where, in particular cases, application would not be compatible with statutory objectives.

In the case of the Clean Air Act, the inability to develop a finely-tuned regulatory program within the statutory deadlines was recognized early by EPA and the States. As a result, many States, with EPA sanction, included variance provisions to assure that requirements would not be applied to individual sources where unnecessary to fulfill the statutory directives. Those provisions stimulated a great deal of litigation, culminating in a recent opinion of the Supreme Court affirming the validity of variance procedures. In the case of the Water Act, EPA established variance procedures in its guidelines for 1977 effluent limitations but did not provide similar procedures in its 1983 guidelines. In the case of both Acts, EPA has not provided a mechanism whereby new source standards may be varied in appropriate cases.

In my opinion, these omissions are not justified. Fairness requires that, at a minimum, EPA allow interested parties to demonstrate that application of a new source standard or a 1983 effluent guideline to a particular facility is not consistent with the Act. If unique facts and circumstances—not considered when the general regulation was adopted—dictate a different requirement, EPA should establish it for the particular facility. The burden of coming forward with evidence to support a variance and the burden of proof would, of course, be on the moving party. Establishing these procedures would not create unbearable regulatory burdens but would assure that the statutory objectives are in fact carried out in all cases.

Another area deserving attention is the influence judicial decisions have had on the EPA regulatory program.

Under both the Clean Air and Water Acts, interested members of the public may file citizens' suits in District Court to require the Administrator to perform a "non-discretionary duty." In addition, the Administrator's rulemaking orders are subject to judicial review in the United States Courts of Appeals. As a result of suits instituted by environmental and industrial groups, the Courts have decided far-reaching questions of statutory interpretation. In certain cases, EPA has been directed to conduct extensive rulemaking to set requirements for previously unregulated activities.

Generally, only those who *challenge* agency action are involved in litigation. Others, whose rights might be significantly affected by the outcome of litigation, cannot participate for the simple reason that they lack actual knowledge that a suit has been instituted. This situation should be remedied. The interests of EPA and the interests of a petitioner or complainant may be different from those of other interested parties. Similarly, the arguments may be different. Accordingly, the opportunity for broad participation by the public in the Courts may be of equal importance to such participation before the agency. This is particularly true since, after a judicial decision is rendered, there is no opportunity to challenge the result except to relitigate the issue.

Broader participation in litigation would assure that all relevant viewpoints are considered by the Courts before interpreting the complex and comprehensive acts administered by EPA. Future litigation might be avoided if all interests are represented in the initial litigation. Thus, I believe that consideration should be given to establishing by statute or regulation a procedure for early public notice of judicial review and citizens' suits. Such notice would allow those whose interests would be affected by the litigation to intervene or file *amicus* briefs, as appropriate.

I would like to conclude my remarks with a few observations about the Water Act discharge permit program under which the requirements detailed in EPA promulgated regulations are applied to individual facilities.

Except in those States having EPA approved programs, discharge permits are issued by the EPA Regional offices. My experience has been that the EPA Regions may have a tendency to "go their own way" and should be subject to more control from EPA in Washington. For example, while a foolish consistency may be the hobgoblin of little minds, I find no reason why the format and standard terms of permits should vary from EPA Region to EPA Region. Nor do I find justification for each Region developing its own unwritten practices and policies, as was my experience with the discharge permit program prior to the time effluent guidelines were promulgated by EPA.

EPA regulations establish procedures for adjudicatory hearings on any permit issued by the Region. Under these regulations, initial decisions are rendered by the EPA Regional Administrator, and questions of law are decided by the General Counsel. The Presiding Officer at such a hearing, who is an Administrative Law Judge, is merely a fact-gatherer.

I am concerned that the practice calling for initial decision by the Regional Administrator may prove to be unfair. First, the procedure violates the principle that he who hears must decide. Second, the Regional Administrator may be called upon to decide issues challenging policies that he directed his staff to implement. Third, because of limited manpower, I believe there is a danger that the Regional Administrator will look to the Enforcement Division of the Region—a party to the adjudicatory hearing and the defender of the contested permit terms—for assistance in preparing his initial decision. I see no alternative to this practice, however, given the few Administrative Law Judges assigned to the agency. Presently, EPA has three Administrative Law Judges handling several hundred permit cases. If the number of Judges can be increased, I believe it would be desirable for EPA to change its regulations to provide that Presiding Officers at adjudicatory hearings render "initial decisions" or at least "recommended decisions" for the Regional Administrator.

A final area of concern to me involves the position that the EPA General Counsel has taken in certain legal decisions rendered under the adjudicatory hearing regulations. Several times, the General Counsel has refused to consider a question of constitutional law posed by a party to an adjudicatory hearing on the grounds that such questions are "more appropriately" addressed in the United States Court of Appeals. First, I believe this response encourages unnecessary litigation. Second, it is an abdication of the agency's responsibility to assure that its activities are conducted in a manner which conforms to constitutional requirements. Finally, where such claims relate to the procedures followed by the agency, there is clear judicial authority for the agency to modify its procedures in the interests of justice.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF RICHARD E. POWELL

This Subcommittee properly recognizes that the Congress must be concerned not only with the substantive merits of federal legislative action, but also with whether the administrative and regulatory agencies which it creates function fairly and efficiently and within the scope of their legislative mandates. Hence, a major focus of these hearings is to examine the operations and procedures of certain particularly important federal agencies, including the Environmental Protection Agency ("EPA").

There are at least three ways to improve the totality of the regulatory functions which are encompassed within the EPA:

(1) The regulatory functions should be restructured either to give EPA's substantive rule-making authority to an independent body, or at a minimum, to place EPA's research and development functions in an independent agency.

(2) A cost-benefit analysis, at least equivalent to the type of analysis required under the National Environmental Protection Act, should be required prior to the adoption of any environmental regulation.

(3) There should be a clear delineation between federal and state rules in the environmental field, which is honored in practice as well as in theory.

I will discuss each of these suggestions briefly in the remainder of this statement.[1]

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[1] The opinions expressed herein are my own. Most of my experience in the environmental field has been in the representation of regulated parties in areas relating to federal and state regulations pertaining to clean air.

I. RESTRUCTURING OF THE EPA

I am sure it is everyone's goal to achieve environmental regulations which are objective and based upon the most accurate scientific data obtainable. But I seriously question whether that goal can be achieved when the entire range of relevant regulatory functions are placed with a single Administrator, as is the case under the Clean Air Act. Thus, the Administrator is singly responsible for EPA's enforcement activities, its substantive rule-making authority, and the research and development activities which are necessary to develop an information base which is adequate for rational rule-making. Yet there is, inherently, a "conflict of interest" in being both a vigorous enforcement and rule-making agency, on the one hand, and an objective evaluator of the information base, on the other hand. To the extent that such conflicts occur (for example, where the information base is not adequate to support any rational regulatory action, but there is pressure to take some action), it would appear that regulatory action gets taken on undefined "policy" grounds. In other words, it is easier to defend vigorous, if mistaken, regulatory actions than to defend inaction on the basis of inadequate information. But if, in fact, that is the process underlying particular regulatory actions, at least the public and the Congress ought to know it. And the process would be more clearly seen and understood if it did not all occur within the confines of a single agency.

There are at least two methods by which the federal environmental regulatory process could be made more open and objective.

One would be to adopt a regulatory structure similar to that in effect in Illinois and some other states. Under the Illinois Environmental Protection Act, three separate, independent agencies were created: (i) the Institute for Environmental Quality, which is essentially the research and development agency; (ii) the Environmental Protection Agency, which is essentially an information gathering and enforcement agency which can and does *propose* substantive regulations; and (iii) the Pollution Control Board, which has the sole authority to promulgate substantive regulations and which also judges and decides enforcement actions and "variance" proceedings. Before it can adopt substantive regulations, the Pollution Control Board must conduct at least two public hearings, at which interested parties can examine or contest the technical and economic rationale for any proposed regulation. Thus, there is at least the opportunity to assure that technical reality has an impact in the regulatory decision-making process. If the technical realities are ignored, there is at least a record to establish that fact if either judicial or legislative relief is sought.

A second method which might be adopted would be simply to put EPA's research and development functions into a separate, independent agency, which would be responsible for developing and evaluating the technical base for any regulatory action. If the research and development agency is not responsible for final regulatory action, there is a much better chance that it will be fully objective in collecting, evaluating and disclosing relevant data. The pressure of achieving other goals would not be present to tempt an independent agency to unduly color or suppress relevant data. Even if second change were to be adopted, I would still recommend that the EPA be required to hold adequate, meaningful public hearings prior to adopting substantive regulations. Without such hearings, it is never fully possible for the Congress, the courts or the public to be certain whether any particular regulation is rational.

When EPA was first created, the need for expedited action may arguably have been such that there was not the time required for full public hearings. But any such need based on expediency surely has passed by now, and is overwhelmed by the need for public hearings to assure that regulatory actions are rational and based on adequate knowledge and understanding.

To illustrate that my concern with EPA's present regulatory process is not purely hypothetical, let me briefly review its position in two important areas.

Ambient air quality standards were established for particulate matters and sulfur dioxides on the basis of studies indicating, as I understand it, *only* that health effects were observed when ambient concentrations of either occurred *simultaneously* with substantial concentrations of other pollutants. However, enforcement of the standards proceeds on the assumption that particulate matters and sulfur dioxides are non-interacting pollutants with independent impacts. Even more importantly, states have been led to adopt emission limits for various sources in light of their contribution of a *single* matter and without regard to the source's impact upon total ambient concentrations. Thus, the emission limits

adopted in State Implementation Plans are not necessarily compelled by requirements of the public health or welfare. Yet I doubt that many, if any, states are really aware of this because the technical base for the EPA's ambient standards has not been adequately exposed or considered. At the same time, the economic and social impacts of attempting to meet those emission limits have been enormous. Clearly, a different "mix" of emission limits, with different economic and social impacts, might have been adopted by the states if they were fully aware of the fact that the evidence does not compel any finding of adverse health effects due either to particulate matters or sulfur dioxides *alone.*

Another area where regulatory actions appear to be underway without a rational technical foundation concerns the so-called issue of "sulfates". Although the EPA has not set any ambient air quality standards for sulfates because of an considering modifications of sulfur dioxide regulations, largely because of the belated recognition of the nation's energy emergency, that direct control of sulfur stantial adverse health effect due to sulfates and it has cautioned states which are belated recignition of the nation's energy emergency, that direct control of sulfur dioxide from electric generating plants is an effective strategy for controlling sulfates. The evidence, however, does not support a conclusion that such plants are the primary source of sulfates. Moreover, certain EPA data tends to implicate nitrates, rather than sulfates, as a cause for concern; and strategies which are recommended to control sulfates may actually increase ambient nitrate concentrations around power plants and thus be counterproductive.

By changing the present process underlying EPA's regulatory actions, the hope is that there would be full exposure and consideration of the relevant data base and, therefore, a more rational foundation for regulatory action in the environmental field.

II. NEPA ANALYSES OF CLEAN AIR REGULATION

The EPA has, of course, succeeded in convincing some Courts of Appeals that, unlike any other federal agency, it does not have to perform the type of analysis required by the National Environmental Protection Act. While I still find it difficult to comprehend how, in effect, the word "all" in NEPA has been construed to mean something other than all, the more important question is whether clean air regulations could benefit from a NEPA type analysis. Here, it is difficult to comprehend how the public is benefitted by a NEPA analysis of whether to construct a new post office, build a mile or two of additional highways, or even construct a new nuclear generating plant, but could not be even more benefitted by a NEPA analysis of whether regulations should be adopted which could have the effect of disrupting the entire national pattern of the use of coal, oil and natural gas. To a large extent, the argument offered in support of the EPA position, and accepted by some courts, rests purely on grounds of expediency; that is, that deadlines for achieving federal ambient air quality standards could not have been achieved if EPA had been required to perform NEPA analyses for its regulations. The additional argument that EPA inevitably and impliedly would consider NEPA-type criteria in its deliberations has been disproven by the actual fact that, in connection with the adoption of ambient air standards and approval or disapproval of State Implementation Plans, EPA has taken the position that it is forbidden to consider questions of cost and technology.

In any event, the alleged need for expediency has long passed and it is time, if NEPA has any merit at all, to apply it to the environmental regulatory process, which is clearly one of the most significant regulatory fields in the entire federal area.

A NEPA type analysis would be particularly useful in evaluating current proposals for legislation which would permit the use of supplementary control systems or indeed "dispersion enhancement" techniques, such as tall stacks, as a means of complying with source emission limits. It is virtually undisputed that there are inadequate supplies of clean fuels to allow compliance with clean air regulations in the immediately foreseeable future and it is only slightly less disputed whether there is adequate capacity by scrubber manufacturers to permit installation of those devices within the next few years in adequate numbers to achieve full compliance with emission limits. On the other hand, it is admitted that in many areas of the country the use of either Supplementary Control Systems or tall stacks are totally adequate to achieve compliance with ambient air quality standards. However, the regulatory point of view simply rejects either SCS or tall stacks as a permanent solution, even though their use in appropriate circumstances cannot in any way be tied to an adverse effect on ambient air

quality or health and general welfare. As a policy matter, many regulators simply have rejected the use of SCS or tall stacks as acceptable. That rejection ignores the competing demands for use of the limited resources of low sulfur coal or scrubbers. It also ignores the entire question of what costs are reasonable to achieve improvement in ambient air quality. Ignoring cost altogether might arguably be justified if the data on adverse health effects were compellingly clear or if the country's resources were so vast that we could ignore other valid competing claims. Money spent for control equipment is money which is not available for other equally desirable goals of national policy. Since the health effects evidence is not overwhelmingly clear and since our national resources are not more than adequate to cover all demands which are placed upon them, a cost-benefit analysis is the only rational way for determining what mix of emission control ought to be allowed in order to obtain the most cost effective improvement in air quality.

Hence, it seems clear that Congress sought to require the EPA (or whatever regulatory body ultimately has rule-making authority) to perform a cost-benefit analysis of past regulations and perform a complete NEPA type analysis prior to adopting any new regulations.

III. THE FEDERAL-STATE ROLES

The Clean Air Act indicates that the state should have primary responsibility for meeting ambient air quality standards. In practice, however, the federal EPA, at least in many states, has directly or indirectly interfered to a significant degree with the state decision-making process.

Perhaps this problem area would not be too significant if the federal EPA appeared before state regulatory bodies only as an objective expert presenting technological data for the states to consider and evaluate in their own determinations. However, in my experience, that has not been the role which the EPA has chosen to play. Instead, the EPA appears only as an advocate and presents only that information and data which tends to support its own preconceived views. In this regard, one may consider the history of the EPA's participation in proceedings before the Illinois Pollution Control Board particularly with respect to the question of whether flue gas desulfurization systems were a viable technology. Originally, federal EPA testified before the Illinois Board that flue gas desulfurization systems ought to be proven technology in the future and perhaps within two to five years. Shortly thereafter, there was a dramatic change of EPA testimony unaccompanied by any change in the state of technology. Then, federal EPA claimed that flue gas desulfurization technology was now proven and seemed to base its contention on methodologies which have since been abandoned not only in the field but also in the EPA justification for its position. Many states adopted emission limits for sulfur dioxide in reliance, at least in large part, upon EPA testimony that flue gas desulfurization technology was proven and adequate supplies of clean fuel were available. Most of the systems cited by federal EPA as "proven" were the so-called throw away systems and particularly those which use wet lime and limestone as a scrubber.

Although challenged, the EPA view was that the throw away systems did not create any significant environmental problem. Most recently, however, in testimony before the Illinois Pollution Control Board, a federal EPA witness indicated that throw away systems were essentially a waste of natural resources; created significant leaching problems (that is, the possibility of water or ground pollution); and posed serious questions as to their reliability. This witness' view was that only regenerative scrubbers made sense. Unfortunately, this view was not expressed until after hundreds of millions of dollars were committed for hundreds of throw away systems.

Finally, I want to thank this Subcommittee for the opportunity to present these comments. Unquestionably, the EPA is one of the most significant agencies ever created by the Congress. Its decisions affect not only the basic health and welfare of every citizen, but also directly and materially affect the very significant economic costs and social impacts of achieving a good environment. Indeed, I doubt that the power to so importantly affect the entire public has ever before been granted literally to a single individual to the degree that it has been granted to the Administrator of the EPA under the Clean Air Act and other environmental legislation. Therefore, no effort is too great in the search for a better way of assuring that environmental regulations are as objective as possible and are based upon the most accurate scientific data obtainable.

PREPARED STATEMENT OF RICHARD E. JONES

My name is Richard E. Jones, Associate General Counsel, Carolina Power & Light Company, Post Office Box 1551, Raleigh, North Carolina 27602. I appreciate the opportunity you have provide for presenting the following comments and suggestions relative to the manner in which the United States Environmental Protection Agency carries out its responsibilities.

Over the past four years I have had occasion to observe the administration of EPA's air and water programs both at the rulemaking level and at the level at which the programs are implemented in the field. If my observations are to be of any value to you, they must be candid and frank. Consequently, my remarks will be directed toward the things EPA is doing wrong. I trust this will not be taken by either EPA or by the Subcommittee as indicating I do not believe EPA is doing anything right for without question you have given it a difficult job. The statutes you have asked it to administer are confusing, poorly written and overly complex and the time schedules it has had to meet have been totally unrealistic. In short, given the world in which Congress has forced it to live, EPA has made an incredible effort to live up to its obligations. I think you should be aware of this and of the fact that EPA's staff is overworked. I have not personally met or seen a lazy or underworked employee in the agency. Neither have I run into EPA staffers or administrators who have been anything less than sincere in their desire to do what is in the public interest.

Hard work and sincerity, however, do not guarantee wise decisions. Neither does the mere fact that EPA is under fire from both environmental and industrial groups guarantee proper decisions, although I have heard staff members make statements to the effect that they must be doing something right because both sides disagree with them. Implicit in this is the assumption that if you refuse to give in to pressure, you will be serving the public interest. Unfortunately, where highly complex technical and economic problems are involved this simplistic assumption does not work and is incompatible with the administrative process when functioning at its best. The problem with being right because everyone is against you and because you refuse to give in is that sometimes the environmentalists should win hands down and sometimes those who are being regulated should win hands down. They should win because when all of the facts are fully developed and analyzed, the answer becomes self-apparent to an objective observer.

This brings me to the theme of my remarks—regulatory maturity and accountability. Unless the Environmental Protection Agency becomes more mature in its role as regulator, and unless a sense of accountability permeates the working staff level so that those who are regulated feel they have been treated fairly and justly and that rational and reasonable decisions are being made, it is safe to predict a ground swell developing in the near future which will result in a backlash against environmental regulation which will not be in the public interest.

In theory, the administrative system is a process by which objective decisions are made and implemented in a context of limited authority. A mature attitude toward the process should reflect itself in a conscious, deliberate effort to stay within the bounds of delegated authority and to make the system work to protect the public interest while minimizing any unnecessary impact on those who are regulated.

In keeping with this, it would be nice to feel that EPA fully appreciated the cumulative impact of all the overlapping state and federal environmental controls to which we are subject and assumed a greater burden for justifying the necessity of each new regulation it imposed or report it required. Unfortunately this is wishful thinking, for there is no self-apparent effort being made by EPA to cut through the red tape, to minimize duplication of effort, or to assume a greater share of the burden of proving the necessity and wisdom of particular limitations and requirements.

With these general observations, let me turn now to several more specific indicia of a mature regulatory policy which I do not see reflected in EPA's general approach to regulation.

LACK OF CLEAR COMMITMENT TO CRAFTSMANSHIP

Fundamental to a mature view of the regulatory process is a commitment to craftsmanship in the drafting of regulations and other documents which must

be independently interpreted and understood by diverse parties with diverse interests. It is not apparent to me, however, that EPA has given craftsmanship priority. When ambiguous provisions of regulations have been called to its attention. there has been no sense of urgency in publishing clarifying amendments. A good case in point is the language regarding construction runoff in the Effluent Guidelines (40 CFR, Part 423) for steam electric power plants. Read literally, there is no limitation upon the area to which the regulations apply. Shortly after the regulations were promulgated in October 1974, however, the office responsible for drafting them indicated that they were not intended to cover runoff from the construction of roads or from other ancillary construction activities separated from the main plant. But, to date no amendments have been issued. Consequently at the level at which the regulations are being implemented the construction runoff provision is having to be challenged in each individual permit. To help avoid this sort of ambiguity in regulations EPA should make greater use of the talents of both industry and environmentalists by soliciting limited pre-publication review for clarity and format.

FAILURE TO USE REGULATIONS TO SOLVE OR AVOID PROBLEMS

Failure to use regulatory authority to solve problems where the agency agrees with the solution is particularly frustrating. A case in point is the so-called "net/gross" problem. This involves the question of whether or not you are responsible for removing pollutants which were already in the water when you brought it into your facility. During the rulemaking for the steam electric Effluent Guidelines the industry contended that, particularly with respect to ash sluicing water, they should not be required to remove naturally occurring suspended solids in the intake water. EPA agreed in this particular instance. However, it refused to deal with the matter in the Effluent Guidelines themselves. It chose instead to defer to a generic "net/gross" regulation which it intended to publish. That regulation in its proposed form required jumping through several hoops, including a showing that meeting a "gross" limitation was significantly less costly than meeting a "net" limitation and making other findings which were unnecessary so far as power plants are concerned. A wiser approach to the regulatory process would have been reflected in avoiding a requirement that placed an additional burden on an applicant for a permit when, for one industry at least, the problem could have been solved without complex case by case findings by inserting a few lines in the Effluent Guidelines. This is to say nothing of the burden and potential litigation created by failing to promulgate the "net/gross" regulation, until July, 1975, some ten months after promulgation of the Effluent Guidelines.

I have also seen a tendency in EPA to rely on "informal policy" in lieu of regulations. This is illustrated in the way EPA chose to handle the implementation of Section 316(a) of the Federal Water Pollution Control Act (FWPCA). Section 316(a) provides for establishing a less stringent thermal effluent limitation where it is demonstrated that the otherwise applicable standard is more stringent than necessary for protection of the aquatic community. Under the Federal Water Pollution Control Act there are two types of standards—those based on technology and those based on water quality. The technologically based standards do not place limitations upon thermal effluents from power plants until 1981. However, many state water quality standards could require imposition of thermal effluent limitations by July 1, 1977, or earlier unless they are found to be more stringent than necessary under Section 316(a). Where this is the case, a powerplant could be put in the intolerable position of building cooling towers to meet the mid-1977 compliance date at the same time it was conducting studies to determine whether or not the water quality standards were more stringent than necessary. EPA's legal counsel agreed during the rulemaking that pursuant to Section 303(g) of the FWPCA water quality standards had to be consistent with Section 316(a) and could therefore be no more stringent than required to protect aquatic life as defined in Section 316(a). As a practical consequence, thermal water quality standards would have to be suspended pending a 316(a) determination. The agency, however, at the last minute refused to adopt this view in its regulations and instead has adopted an informal policy to the effect that an applicant will not be required to take steps to comply with thermal water quality standards until after it has had an opportunity to make a biological demonstration pursuant to Section 316(a). This has the unfortunate consequence of leaving everyone in a state of limbo and perhaps subject to expensive and time consuming litigation when the problem could have been solved through

promulgating a simple regulation. It would also have avoided arguments with regional staff members who may not always get the word about the agency's "informal" policies.

INSENSITIVITY TO ADMINISTRATIVE BURDEN

Regulatory maturity should further manifest itself in deliberate efforts to minimize duplicative and unnecessary paper work. Congress had the good sense to spell this out in express terms in Section 101(f) of the FWPCA. Nevertheless, we find ourselves deluged by requests for information which is already available. To illustrate, we have been told that as a first step in enforcement under the Clean Air Act it is agency policy to issue an order under Section 114 which requires furnishing a vast amount of information on a standard form. Filling out the first of these forms which we received for one plant required one man-week of labor on the part of the person who actually filled in the blanks, to say nothing of the time of those in various departments who made input to him. Unfortunately, most of the information contained in the form had little or nothing to do with the problem which precipitated the need for enforcement action in the first place. Faced with problems at other plants caused by malfunctioning pollution control equipment installed to meet the requirements of the Act, we recently learned that additional Section 114 orders would be issued. The initial response to our complaints about the waste and added burden involved in Section 114 orders to produce information was that Washington says you have to issue them before beginning an enforcement action. We have contended that there is no need to issue a formal order to acquire this information because we will be happy to respond voluntarily to particular requests for information which relate to the specific problem EPA is addressing. In addition, identical and sometimes superior information to that required pursuant to the Section 114 form is generally available pursuant to the routine monitoring requirements imposed under state implementation plans which have been approved by EPA.

In my opinion, a regulatory policy sensitive to the burden being imposed would make full use of all available information before demanding that the regulated party go to the time and expense of reproducing in a different form information which is already available to the agency. If the data being supplied to the state under the EPA approved state implementation plan is not adequate for EPA's regulatory purposes, then those requirements should be changed because useless information is being collected.

I am particularly distressed to see EPA going further than it needs to or than it has any business going to assure compliance with substantive standards without an apparent awareness of the burden it is creating. For example, the regulations EPA adopted to implement Section 119 of the Clean Air Act (relating to Clean Air Act compliance date extensions for facilities ordered by the Federal Energy Administration to switch from gas or oil to coal [40 CFR, Part 55]) require EPA approval of a company's coal supply and pollution equipment contracts prior to their becoming effective. Analogizing from the experience many states have had in conjunction with EPA review of their legislative authority causes one to shudder at this sort of involvement in private contractual matters. It leads me to believe that there is less than adequate appreciation for the limits of a regulatory agency's legitimate authority.

LACK OF RESPECT FOR LIMITATIONS OF AUTHORITY

This brings me to the issue of regulatory accountability. It is, in my judgment, the cornerstone of the proper functioning of our administrative law system. Accountability equates with a healthy respect for, and recognition of, the limited authority associated with every regulatory agency. Regulatory maturity is perhaps evidenced most clearly in the attitude expressed by an agency's staff toward its authority. Ideally, each staff member in a healthy and mature regulatory agency would be trained to deliberately relate every decision he made to the express authority of a statute or regulation. In order to enforce this sort of staff respect for an agency's limited authority, there should always be a readily available means for requiring a statement of authority and justification for imposing or proposing to impose any particular requirement without undue procedural hardship or the expense of litigation. Unfortunately, my experience with EPA has not revealed this sort of staff awareness of the agency's limited authority, nor is there a procedure for requiring a statement of authority short of going the full

appellate route. As a general observation, and perhaps this more than anything else has led me to shape my remarks around the concept of regulatory maturity, the attitude communicated by EPA staff is that their job is to protect the environment whenever and wherever they believe it needs to be protected, regardless of what the statutes authorize. This sort of attitude requires those of us who represent clients subject to EPA regulation to be continually on our toes and to utilize and threaten to utilize legal remedies far more frequently than should be necessary and, worse yet, to give in to a form of subtle blackmail out of a pressing need to obtain a permit or other clearance so that our clients can go about their primary business.

An excellent example of what can happen where a proper respect for limited regulatory authority is lacking is the experience power companies have had in the Southeast. Shortly after proposed Effluent Guidelines for the steam electric power plant point source category were published in March of 1974, EPA's Regional Office prepared a permit for use with power plants containing limitations considerably more stringent than those in the proposed regulations. This resulted in the companies in the region forming an ad hoc group to deal with the problem. After several meetings and ongoing discussions the regional staff began to retreat from its earlier position that it had virtually unlimited authority to impose any requirement it felt necessary to protect water quality and to require applicants to accept permits which gave the Regional Administrator the right to unilaterally impose additional requirements after the time for appeal of the permit had run. Efforts to avoid accepting permits reflective of this overreaching by EPA have taken over a year and one-half and have resulted in requests for adjudicatory hearings relative to virtually every permit issued to power plants in the region. As a consequence of the attempts by EPA staff to exceed their legitimate authority, permits have been issued to only a small fraction of the power plants in the region and all plants have been delayed in getting plant modifications under way. This penalizes the companies in that when a permit is finally issued they will have much less time than they would have had originally to comply with the July 1, 1977, deadline for most plant modifications.

A similar tendency to overstep the limits of authority is found in the degree to which many on EPA's staff seem willing to proceed without having made reliable factual findings. In the real world, decisions which are not backed up by hard facts can lead to the expenditure of millions of dollars, particularly where the pressures of more than one agency are involved. Illustrative of this is Carolina Power & Light Company's experience with its Brunswick Nuclear Plant where without the benefit of site specific empirical studies and without allowing the Company time to collect data, a cooling system which had been mandated by the Federal Water Quality Administration was declared environmentally unacceptable by the Nuclear Regulatory Commission with EPA's encouragement and support after it was built but before it ever operated. Cooling towers were required at a currently estimated expense to CP&L ratepayers of in excess of $20 million each year for the life of the plant. The Company, however, went ahead and collected the data at the same time it started complying with the cooling tower requirement and now is able to show by the data collected for the past year and one-half that the estimates of the impact of a once-through cooling system were off by orders of magnitude.

Where both a procedure and a realistic time schedule for gathering data are available, and where a meaningful opportunity to submit opposing views of factual issues to an objective trier of fact is provided, there is a sense of fairness and one does not object nearly so much to subjecting his will to that of the government in the name of the public interest. Where, however, the feeling exists that the facts have not been fully laid out or developed and that the regulatory agency is less than scrupulously concerned that it not overstep the limits of its authority, the tendency is to resist everything it is trying to do. Assuming this is true, it follows that it is in the public's interest for EPA and other regulatory agencies to develop a healthy respect for the agency's limited authority, particularly at the staff level.

UNDUE INTERFERENCE WITH STATE PROGRAMS

Related to the issue of accountability and limited authority is EPA's attitude toward the role of states in administering air and water programs. Both the Clean Air Act and the Federal Water Pollution Control Act are premised on the notion that the state has primary responsibility for pollution control. This

primary responsibility was recently affirmed by the Supreme Court so far as the Clean Air Act is concerned in *Train v. NRDC*, —— U.S. ——, 43 L.Ed.2d 731 (April 16, 1975). EPA's administration of these Acts, however, does not evince a healthy respect for the primary role of the states nor give them much latitude or discretion. By way of example, the Federal Water Pollution Control Act provides that the Section 402 National Pollutant Discharge Elimination System (NPDES) permit program can be delegated to the states. Generally speaking, however, states have had tremendous problems getting EPA to approve their underlying statutory authority for administering the NPDES program, and have experienced considerable frustration in attempting to satisfy EPA staff members with proposed legislative packages. My own experience with this insofar as delegation of NPDES authority to North Carolina is concerned was to find EPA threatening to withhold approval of the North Carolina program if a provision in the state statute was changed which had nothing to do with the statutory authority required for NPDES approval. This sort of overreaching is disturbing.

I have also found, with respect to the NPDES delegation, that the proposed Memorandum of Agreement between the Regional Administrator and at least the states of North and South Carolina gave EPA complete power to write any provision it chose into a state issued permit and provided no means for either the state or the permittee to challenge EPA's decision. This blanket authority to require that state issued permits be fully satisfactory to EPA and that they contain whatever conditions EPA dictates goes far beyond the limited authority given to it under Section 402(d) of the FWPCA. Section 402(d) limits EPA's power following program delegation to that of vetoing permits issued by states only upon finding that they are outside the guidelines or requirements of the FWPCA. It does not permit EPA to second guess state determinations as the proposed North and South Carolina memoranda of agreement did.

The manner in which NPDES authority has generally been delegated to states also has the practical effect of denying the permittee his statutory right to a hearing relative to EPA's input to the ultimate decision. Permits presently issued by EPA are subject to 40 CFR, Part 125 which expressly provides that an applicant has a right to an adjudicatory hearing to challenge any terms or conditions of an NPDES permit with which he is dissatisfied. But once the NPDES program is delegated to the states, EPA can continue through threat of veto to impose conditions in state issued permits and the permittee will have no right to a hearing before EPA and no clear means of judicial review. He will have to fashion a judicial remedy and hope that he can get a hearing in the course of that review.

Another area in which examples of overreaching are found relates to EPA's interface with the states' interpretation of their own water quality standards. The primary enforcement mechanism in the Federal Water Pollution Control Act is the technologically based effluent limitation. Theoretically, these are the most stringent standards which can reasonably be imposed because they are based on what technology can accomplish. However, there is also a backup system consisting of state water quality standards which were the primary control device under the Federal Water Pollution Control Act prior to its amendment in 1972. These standards are promulgated by the states but are subject to EPA approval. They are ambient type standards relating to the quality of the water in the receiving stream after mixture with any pollutants discharged into it. Generally, these standards are expressed as numerical concentrations which cannot be exceeded. They are state standards. Routinely, they would be incorporated into NPDES permits as a result of a state's certifying, pursuant to Section 401 of the FWPCA, that they should be incorporated in the permit. EPA, however, even where a state has not indicated that its own water quality standards are applicable, has been setting limits based on them in NPDES permits and in several instances has ignored a state's interpretation of its own standard and insisted that the standard authorizes an even more stringent limitation than the state says is permissible or required.

A further example of interference with the primary responsibility of the states for pollution control concerns variances under the Clean Air Act. Recently, the Supreme Court in *Train* v. *NRDC* (*Supra*) ruled, contrary to several circuit court opinions, that variances were permissible under the Clean Air Act even after the date state implementation plans had to be achieved (generally May 31, 1975) so long as the variance did not interfere with maintaining national ambient air quality standards. In effect, this meant that procedurally there was a way to give justified relief in cases in which sources were unable to comply with

the Clean Air Act's very tight statutory deadlines. EPA, however, chose not to let the Supreme Court overrule its earlier determination that variances were not permitted. In essence, it led the states to believe that it would be virtually impossible to get it to approve a variance as a revision of a state implementation plan as required pursuant to the Supreme Court's reasoning. In short, EPA convinced the states that it was not worth their trouble to try to take advantage of the relief the Supreme Court decision afforded because EPA was going to make it too difficult to succeed. This is heavy-handed. EPA's only legitimate interest is in ascertaining whether or not there is a reasonable basis for concluding that national ambient standards will be achieved. To circumvent this limited authority, EPA apparently implied to the states that it would require an unreasonable degree of proof in order to justify variances which in most cases would be for relatively short periods of time and would not justify the expense of the extremely sophisticated modeling necessary to prove beyond a reasonable doubt that there would be no interference with ambient standards. In the case of Carolina Power & Light, this will result in issuance of several compliance orders and formal findings that we are violating the law where in fact the noncompliance is beyond our control and caused by the fact that installed pollution control equipment is not functioning properly. By administrative fiat, in a case in which everyone acknowledges the Company has acted in good faith, we are deprived of an opportunity to employ a procedural device (that is, a variance) which would allow us to comply with the law.

This general tendency to override the states and to threaten them with disapproval of proposed plans which require EPA approval is distressing. Among other things, it makes it difficult to deal with the states because while they themselves might agree that a particular course of action is permissible and in the public interest, they are reluctant to move forward without EPA's prior approval. And if EPA does not give its approval, there is generally no practical way to challenge the decision which, in this context, is frequently made without the development of an adequate factual record.

ERRORS OF JUDGMENT IN RULEMAKING

I would like now to make an observation or two about rulemaking. In my opinion, a mature and accountable regulatory policy should be marked by willingness to seek out the advice and comments of those who must live on a day-to-day basis with the regulations and programs developed by the agency. This is not to say that the fox should be allowed to guard the hen house, but it is to say that prior to drafting proposed regulations EPA should have a series of meetings with those who will be most affected by them and should spend whatever time is necessary to acquaint themselves with operations of the type for which they are drafting regulations. My own impression from the contact I have had with EPA rulemaking is that the technical staffs are very bright, but frequently they are young and lacking in day-to-day operational experience with the types of facilities for which they are drafting regulations. Further, to compensate for the lack of data or the lack of time to acquire data, I get the feeling that from an engineering standpoint there is too great a willingness to be conservative about the degree of control required, on the one hand, but to liberally assume, on the other, that a technology which has been tried on a different scale and in a different context has direct transferability. Mistakes of a technological nature in this context are not only extremely costly, but they, perhaps more than anything else, create cynicism and lack of respect for all environmental controls, not only in industry but also among the public as the cost of these mistakes is passed through.

While perhaps less crucial than its substantive regulations, EPA's procedural regulations are also extremely important. Because they determine the rights to be accorded those who are subject to regulation, and because they provide the means for resolving disputes, it is essential that they be clear and that they work. Procedural regulations, however, are frequently not submitted for review prior to implementation. This creates serious problems, since, depending upon the perspective from which one approaches a particular regulation, it may or may not appear to provide for various situations and contingencies. One very important example of a regulation EPA did not circulate for comment prior to promulgation was its amendment to 40 CFR, Part 125 promulgated in July of 1974. This is the regulation pursuant to which NPDES permits are issued. In the process of amending the regulation relative to adjudicatory hearings, EPA devel-

oped a bifurcated hearing process for adjudicated issues. Under the procedure factual issues go to hearing officers and are handled at a regional level while legal issues go to Washington. Unfortunately, most cases involve complex issues of fact and law interwoven in a single fabric. Not only is it difficult to separate the factual and legal issues, but the provisions for becoming involved in adjudicatory hearings are such that the time for intervening could come and go and one would never be aware of the fact that a key legal matter having tremendous implications nationally had been certified as a legal issue. Even after the issue had been decided, one might not know about it since EPA is not even publishing notice of decisions reached as a result of adjudicatory hearings or as a result of legal questions being certified to the general counsel.

A situation similar to the publication of procedural regulations without opportunity for comment is presented by the use of standard permit forms. At some point the Washington staff developed a format for NPDES permits under the Federal Water Pollution Control Act and sent them out for use. The standard format permit contained considerable boiler plate language which the staff administering the program at the regional level say they cannot change. As a practical matter, this means that it is necessary to live with defacto regulations which have never been subject to public hearing and which cannot be appealed as generic rules. A challenge would require full-blown judicial appeal. Because of the cost, one is reluctant to take up an issue which is important but not crucial.

CONCLUSION AND RECOMMENDATIONS

In my testimony I have focused not upon the major substantive disputes surrounding the Federal Water Pollution Control Act or the Clean Air Act, but upon things which affect the day-to-day operation of EPA programs. In all candor, the major problems and frustrations associated with the administrative process grow out of what happens at the staff level where regulations are conceived, drafted and implemented more than at the level at which administrators approve them and resolve major disputes. When the problems are major, they can usually be handled because there is a means to obtain judicial review and there is in dispute a substantial enough question to warrant the time and expense. The problems on which I have focused are those which in and of themselves may not warrant legal action but which in the long run so frustrate those who are regulated that they are led to utilize the power available to them to do away with the irritant altogether.

Under the rubric of regulatory maturity and accountability, I have been addressing the nuts and bolts issue of how one controls a regulatory agency in the Federal government. Top level administrators come and go while career staff carry on year after year. In order to foster a greater sense of accountability in the regulatory process at the work-a-day level, both in rulemaking and in the implementation of regulations, I have two relatively simple suggestions. The first is that where complex technical regulations are concerned, EPA be required to meet with a representative group of those who will be subjected to the regulations for the purpose of ascertaining what practical impact the regulations will have and that thereafter, prior to the final promulgation of such regulations, a public hearing be held at which some form of cross-examination of EPA's technical experts is permitted. Such hearings would not of necessity have to turn into circuses and cross-examination would not have to be unlimited. It could be fairly disciplined and in appropriate circumstances could be confined to questioning by an independent technical expert hired for the purpose of helping to develop a full and adequate record.

The second suggestion is that regulatory agencies such as EPA be required to develop procedures pursuant to which any party subject to regulation by the agency can demand and receive a reasonably detailed statement of factual and legal authority for the imposition or threatened imposition of any proposed requirement or for the refusal or threatened refusal to take any action which the party alleges the agency is obligated to take. This procedure would be in addition to any opportunity for a formal adjudicatory hearing or judicial review which might be available. It would have a disciplinary effect on regulatory staff members which in my opinion would be healthy, productive and would lead to more objective decision making.

This concludes my prepared testimony. Thank you very much for the opportunity to testify.

PREPARED STATEMENT OF TURNER T. SMITH, JR.

Mr. Chairman and members of the Subcommittee. My name is Turner T. Smith, Jr.[1]

The Subcommittee has asked that we focus on the administration by the Environmental Protection Agency (EPA) of the environmental programs for which it has responsibility, commenting particularly on its administrative procedures and the propriety of its exercise of delegated power. In responding, I will direct my comments to EPA's implementation, for stationary industrial sources, of its two main programs—air and water pollution control—since I have little experience with other EPA programs.[2]

This Committee's inquiry is an important one. As Justice Jackson has said: "The rise of administrative bodies probably has been the most significant legal trend of the last half-century. . . ." [3] That trend has continued apace.

Recent environmental laws are part of a new wave of administrative control breaking over the private sector. They raise large and fundamental issues. The economic stakes, for example, are huge. EPA's water pollution regulations under the Federal Water Pollution Control Act (FWPCA or the Water Act) will, for the electric utility industry alone, cost about $6.6 billion by 1983, even by EPA's estimates.[4] And implementation of EPA's current policy as to one air pollutant, SO_2 will impose capital costs on that same industry of at least $6.5 billion by 1980,[5] yielding a total of $13.1 billion at stake for these phases of regulation in this industry alone.[6] The industry is already wracked by acute financial crisis because of prolonged inflation. Ever-increasing construction costs, high interest rates, burgeoning fuel prices, as well as consumer and sometimes regulatory resistance to needed rate increase have combined to jeopardize the ability of electric utilities to raise the capital needed to meet ever-increasing electric energy needs and to backfit for present water and air pollution control regulations. This capital crunch is compounded by the substantial national shortage of capital projected over the next decade, a shortage that will be further aggravated by the federal government's borrowing to cover deficits in the federal budget. And, if enough new capacity is not built now, it will not be available when needed in the years ahead, to the nation's severe detriment.

Not only are the economic stakes high, many of the new environmental controls raise fundamental long run questions of social impact. Air and water quality ambient standards, for example, have direct land use implications, since new industrial, residential or automotive pollution sources will be effectively zoned out of many areas when those ambient limits are approached, as they already have been in many cases.[7] These land use constraints are, however, only a belated legal articulation of more fundamental natural limits on human aglomeration. As such, they have the potential for radically restructuring the geography of both our urban and our rural areas.

Delegations of lawmaking power with such awesome scope and consequences, while frequently necessary to cope with the complexity of modern society, are

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[1] A member of the law firm of Hunton, Williams, Gay & Gibson of Richmond, Virginia and Washington, D.C.

[2] My practice is in the environmental, nuclear and energy field, largely representing electric utilities.

[3] *FTC* v. *Ruberoid Co.*, 343 U.S. 470, 487 (1952) (dissenting opinion).

[4] 39 Fed. Reg. 36185, (1974) (Preamble to EPA's § 304(b) effluent limitation guidelines and § 306 standards of performance for the steam electric generating industry). A group of 74 electric utilities challenging aspects of these EPA regulations (in which litigation my firm and I are participating) believe the true 1983 cost to be closer to $12.7 billion. See Brief for Petitioners at 69–70, Appalachian Power Co. v. Train, No. 74–2096 (4th Cir., filed Oct. 2, 1974).

[5] An EPA estimate of May 7, 1975 is reported in *Hearings on S. 1777 Before the Senate Comm. on Pub. Works*, 94th Cong., 1st Sess. (June 12, 1975), "Preliminary Report of the Electric Utility Industry Clean Air Coordinating Committee" at 14 (Supp. 1, May 28, 1975), submitted in Testimony of Donald G. Allen.

[6] If the higher industry estimates prove correct, these EPA actions threaten the electric utility industry with total expenditures of well over $20 billion by the early 1980's. Such an investment would exceed 20% of the total business expenditures for new plant and equipment in 1973, which were $100 billion. *Economic Report of the President* 296 (1974). It would also represent over one-fourth of the total capital of $92.9 billion in 1972 of investor-owned electric utilities. Edison Electric Institute, *Statistical Year Book of the Electric Utility Industry* 60 (1972).

[7] These impacts, as well as EPA's administrative problems, will be dramatically magnified if an arbitrary tertiary set of ambient standards is demanded by the Congress or the courts under "no significant deterioration" principles.

legitimized only through careful control by Congress and the courts. Congressional oversight is one such tool and contributes to a vital tradition of continuing reassessment of our administrative agencies.[8]

It is an opportune time to reassess EPA's performance, in particular, since the first round framework of the Clean Air Act (the National Ambient Air Quality Standards (NAAQS), and the State Implementation Plans (SIP's)) and of the Water Act (the water quality standards, effluent limitations guidelines and standards of performance) is now largely in place and being implemented. There are, of course, more complex "dynamic" second level problems yet to be addressed as the initial set of controls is applied over time, but the difficulties faced by the regulated and the regulators alike in the more simple "static" first phase suggest that we pause now to see where we have just been.

A. EPA—THE AGENCY PERSONNEL

Let me begin with a necessarily subjective and impressionistic view of the agency personnel themselves. The EPA staff, particularly the General Counsel's Office with whom I work most often, is made up, on the whole, of sincere, hard-working, fairminded, and highly competent[9] people. Many of them are relatively young and new to public service. They must struggle with excessively detailed, badly drafted and ambiguous legislation of byzantine complexity under impossible Congressional deadlines.

There are, of course, some—the regional, non-legal people seem most susceptible in this regard—who let their partisan zeal outrun their good sense, perhaps from inexperience at having to work within an essentially legal framework of constraining regulatory and statutory authority or perhaps from timidity at exercising fully and flexibly their proper discretionary power. And the highest-level decisionmakers too often let wishful thinking obscure hard scientific or technological fact. But on the whole, EPA's personnel are among the best I have encountered in government service.

That being said, however, I must add that I by no means always agree with their method of administering EPA's air and water programs, much less their substantive decisions in doing so. I should note in fairness, however, that much of my concern in this regard stems from substantive and procedural defects (or just plain sloppy draftsmanship) in the statutory scheme, for which the Congress, not the agency, must answer. I turn now to EPA's faults.

B. EPA'S MAJOR FAILINGS

EPA has, in my judgment, made a number of major policy errors that have frustrated efficient and faithful implementation of the Clean Air Act and the Water Act. In most cases these EPA errors have stemmed either from a too narrow EPA interpretation of ambiguous statutory language, the effect being to rob the statutory framework of necessary procedural or substantive flexibility, or from inadequate rulemaking procedures.

1. The NEPA debacle

First, EPA has resisted, all along the line, being required to engage in the sort of meaningful and publicly articulated rough "balancing" of all those factors (both costs and benefits) relevant to its regulatory decisions. One way EPA did so was by refusing to apply the mandate of the National Environmental Policy Act to its own environmental management activities.

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[8] For governmental critique, *see e.g.*, President's Advisory Council on Executive Reorganization, A New Regulatory Framework: Report on Selected Independent Regulatory Agencies (1971); J. Landis, Report On Regulatory Agencies to the President-Elect, Submitted by the Chairman of the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary, 86th Cong., 2d Sess. (Comm. Print 1960); Commission on Organization of the Executive Branch of the Gov't, Report of the Comm. on Independent Regulatory Comm'ns (Hoover Comm'n 1949); Report of the President's Comm. on Administrative Management (1937). For scholarly critique, *see e.g.*, Freedman, "Crisis and Legitimacy In The Administrative Process," 27 Stan. L. Rev. 1041 (1975) (citing many of the academic critiques); Wright, "Beyond Discretionary Justice," 81 Yale L. J. 575 (1972). For polemical critique, *see e.g.*, E. Cox, R. Fellmeth, & J. Schulz, "The Nader Report" on the Federal Trade Commission (1969).

[9] EPA has suffered a staggering, and virtually uninterrupted series of reverses in the courts. I attribute much of this record, however, to the rules requiring EPA to be represented in oral appellate arguments in crucial cases raising complex technical and policy issues, by all too often young and inexperienced lawyers from the Justice Department.

NEPA is "the broadest and perhaps most important of the recent [environmental] statutes."[10] *Calvert Cliffs' Coordinating Committee, Inc.* v. *AEC*, 449 F.2d 1109, 1111 (District of Columbia Cir. 1971) (hereafter cited as Calvert Cliffs'). It is a basic charter requiring decisional rationality by all federal agencies engaged in environmental management. Since NEPA's passage, the country has been committed to agency action that makes the optimal use of scarce national resources.[11] The necessity for such an informed allocation of national resources grows daily.

The plain language of NEPA requires "all agencies of the Federal Government" to prepare an environmental statement prior to taking any major Federal action significantly affecting the quality of the human environment. There are no words of exemption for EPA or any other Federal agency.

The promulgation of national regulations for pollutant emissions is indisputably a major Federal action significantly affecting environmental quality. Indeed, few Federal actions will have a greater long-run impact on the human environment, for good or ill, than EPA's decisions regulating the release of environmental pollutants to the air and water. Furthermore, the vast social resources needed to comply with these EPA regulations will be irreversibly and irretrievably pre-empted from use for other social and environmental objectives.

Yet EPA has set its substantive air and water quality restrictions without publishing a NEPA environmental statement and without conducting the "systematic balancing" of costs and benefits and of alternative actions which Calvert Cliffs' held necessary to ensure that "the most intelligent, optimally beneficial decision will ultimately be made." "Tunnel-vision" is as deplorable an affliction at EPA as elsewhere.

Compliance with NEPA by EPA would not have interferred with implementation of Federal environmental programs. It would have facilitated them eliminating false starts by early ventilation of technical and policy premises that in many cases later turned out to be erroneous or unwise.[12]

One observer, writing in the National Journal, noted in this regard, that:

> Environmental lawyers say also that compliance need not, as EPA contends and Muskie fears, bring environmental regulatory programs to a standstill.
>
> Said Roisman: "EPA sounds exactly like the AEC used to sound—crying wolf and claiming all of its programs will go to smash. * * * They're playing right into the hands of the mission agencies and the dam and highway builders by attempting to portray NEPA as an inflexible act with rigid procedures."
>
> The *Calvert Cliffs'* decision, and a number of other cases, Roisman said, clearly indicate that the courts are willing to allow flexibility where an emergency or a deadline exists and that—as the language of the act states—agencies are obliged only to live up to its provisions "to the fullest extent possible."
>
> "The problem is," he said, "EPA is just sitting on its ass, whining and waiting for Congress to bail it out."
>
> Contrary to the contentions of Muskie and the EPA, environmental lawyers argue, the environmental policy act is not incompatible with the environmental regulatory acts that EPA must administer.
>
> "There is no inherent conflict between NEPA and other environmental acts," said Roisman, "except that created by EPA lawyers and Muskie. Baker and their staffs. Whatever 'balancing' the agency does would have to be in relation to its statutory obligations under the Clean Air Act, the Water Pollution Control Act, the Pesticides Act and so forth," said Roisman.[13]

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[10] *See, e.g.*, 115 Cong. Reg. 19009 (1969) where Senator Jackson said: "In many respects, the only precedent and parallel to what is proposed in S. 1075 [NEPA] is in the Full Employment Act of 1946. * * * It is my view that S. 1075 will provide an equally important national policy for the management of America's future environment."

[11] As the Court stated in Calvert Cliffs' 449 F.2d at 1123: NEPA mandates a case-by-case balancing judgment on the part of Federal agencies. * * * The magnitude of possible benefits and possible costs may lie anywhere on a broad spectrum. * * * The point of the individualized balancing analysis is to ensure that * * * the optimally beneficial action is finally taken.

[12] *See e.g.*, the secondary annual NAAQS for SO_2 that as withdrawn (39 Fed. Reg. 11355 (May 7, 1973)), the flap over nitrogen oxide emission limitations due to inaccurate NO_2 ambient measurement techniques (39 Fed. Reg. 15174 (June 8, 1973)), "SIP overkill," and the wavering EPA positions on SO_2 scrubbers, supplemental controls (SCS) and tall stacks.

[13] Barfield, "Environmental Report/Water Pollution Act Forces Showdown in 1973 Over Best Way to Protect Environment," National Journal 1871, 1880–81 (Dec. 9, 1972).

Stability and predictability of the law would also have been enhanced by NEPA compliance when generic environmental standards are set, early in the policy formation process. NEPA's policy of rational environmental management should not have been frustrated by EPA's unilateral exemption from it of the core federal programs that regulate environmental quality.

Congress finally acted to partially exempt EPA action with the Clean Air Act and the Water Act from NEPA.[14] Senator Jackson expressed grave reservations in the debates on the Water Act exemption about the wisdom of insulating EPA from the public, the Congress and the courts, by exempting it from NEPA:

> "[Why should] environmental control programs * * * be exempt from the constraints of environmental laws? Do we exempt civil rights programs from anti-discrimination requirements? Are labor programs exempted from minimum wage and child labor laws? Are law enforcement officers free to disobey criminal laws?
>
> "In short, the question is, 'Who shall police the police?' * * *."

I concur with Senator Jackson and believe the congressional action to have been unwise.

2. FWPCA's balancing test—EPA's missed opportunity

Even though Congress has now granted EPA an exemption from the procedural NEPA requirement that it produce an impact statement, EPA could still have exercised the more limited balancing mandate implicit in such organic legislation as the Water Act.[15]

FWPCA is an immensely complex, often confusing statute. Both its text and legislative history are endlessly convoluted. Neither has much "plain meaning" to shed on a host of substantive issues raised by EPA's efforts to implement the Act. The most basic controversy in the Act's interpretation turns on whether it established "no-discharge" as an end in itself, irrespective of whether total realization of that end would do the country more harm than good. I believe that FWPCA established no-discharge as an end to be vigorously pursued *only* so long as the social benefits of further controls are commensurate with their social costs.[16]

Under FWPCA, EPA's authority to set effluent limitations guidelines and standards of performance comes from the Act's "best practicable" and "best available" technology requirements. These requirements have at their core the term "best." The Act and its legislative history indicate that the "best" technology is that which involves a reasonable relationship between costs and benefits. Thus, FWPCA is in my judgment intended to embody no single-minded anti-pollution imperative, heedless of resulting social consequences. Rather, the Act calls for balancing the benefits of proposed effluent controls against their costs, in order to determine whether those controls should be imposed.[17]

In the pursuit of "best" technology, however, the Act *does not* shackle EPA to any rigid, formalistic cost-benefit study of the sort traditionally performed by academic economists or the Corps of Engineers. Nor does it foreclose regulation just because significant costs and benefits sometimes cannot be quantified. But the Act does insist that the social costs of any particular control technology be imposed only after a focused regulatory effort to ensure that these costs "purchase" social benefits that are at least roughly commensurate. In short, Congress made manifest in FWPCA a commitment to the rule of reason in this country's allocation of its resources toward the elimination of water pollution.

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[14] For an extended argument that EPA is still subject to NEPA's substantive, as opposed to its procedural impact statement requirements, when taking action under FWPCA, see Utility Water Group Comments on EPA's Proposed § 304 Guidelines and § 306 Standards of Performance for Steam Electric Powerplants, Vol. I, Attachment I.B. (June 26, 1974).

[15] The Clean Air Act has similar requirements. The District of Columbia Court of Appeals—when faced with a congressional call for use of "best" technology in the Clean Air Act (§ 111(a)(1), 42 U.S.C. § 1857c–6(a)(1) (1970))—ruled that "[t]he standard of the 'best system' is comprehensive," that EPA must engage in a "balancing analysis," and that the Agency must articulate the "economic costs to the industry" and "the environmental considerations, pro and con which have been taken into account as required by the Act." *Portland Cement Ass'n* v. *Ruckelshaus*, 486 F.2d 375, 385–86 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974). In so doing, the court found evidence in the Clean Air Act of a congressional judgment which appears more explicitly in FWPCA: EPA must not forego the preparation of a NEPA impact statement unless that Act's thrust toward a balancing process in agency decision-making is carried forward by some means other than, but functionally equivalent to, an impact statement.

[16] This issue is currently being litigated in the lawsuit referred to in the note at 2 above.

[17] For a full development of this argument, see Supplemental Brief for Allegheny Power System, Inc., *et al*, as Amici Curiae, *E. I. du Pont de Nemours & Co.* v. *Train*, No. 74–1261 (4th Cir. filed Mar 5, 1974).

3. The need for case-by-case "Fine Tuning" to supplement EPA rulemaking

EPA has, in my judgment, frequently relied too heavily on its rulemaking authority alone, particularly under the Water Act, thus robbing itself of the flexibility for necessary, and congressionally mandated, case-by-case adjustment of its air and water requirements.[18] I believe that FWPCA's regulatory scheme requires flexible implementation. EPA, however, has prescribed instead nationally uniform effluent limitations and standards of performance "to be applied on a uniform basis to all plants within [a] subcategory," [19] regardless of differences among them. The only hint of flexibility is a provision in the 1977 "best practicable" regulations,[20] allowing the permit grantors to consider technical and engineering factors "fundamentally different" from those EPA considered when promulgating its regulations. But this provision does not allow consideration of different facts [21] or of "economic factors." [22] And in any case, this provision is not made available at all for 1983 and new source requirements.

EPA's rigid implementation of FWPCA is contrary to congressional intent and thus predictably unworkable. First, EPA's promulgation of nationally uniform effluent limitations rather than guidelines for *existing* sources exceeds the Agency's rulemaking authority under FWPCA. And the immense and significant variability in the cost and feasibility of closed-cycle cooling at existing power plants make clear that EPA's Procrustean scheme could never realize the Act's substantive purposes. Second, EPA's standards for *new* sources, while within the Agency's rulemaking authority under FWPCA, do not contain the sort of "safety valve" necessary to ensure that the Act's purposes are met in particular cases. Some of the arguments supporting this view of the Water Act are set out in an Attachment (FWPCA Requires Flexible Implementation) to this testimony.[23]

4. EPA's inflexible selection of control techniques

EPA has, unfortunately, interpreted the Clean Air Act to date so as to deprive itself of much needed substantive flexibility—by taking the position that various forms of supplemental controls (SCS) [24] as well as tall stacks can never be appropriated long-term "emission controls" under the Act. I believe that this EPA position, now in litigation, is wrong as a matter of law and unwise as a matter of policy.

At many power plants, SCS can effectively assure that SO_2 emissions do not result in violations of federal primary and secondary standards.[25] Indeed, at present levels of technology, use of SCS where appropriate can provide greater assurance that plant emissions will not cause violations of air quality standards than can scrubbers operating under current regulations.[26] If SIPs could be revised through the mid 1980's to permit the use of complying fuels and SCS on a plant-by-plant basis, it would substantially relieve demand pressures on scarce low sulfur coals and make high sulfur coals from already developed Appalachian and Midwestern site usable in many areas, without allowing violations of the ambient standards.[27]

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[18] EPA originally took the position under the Clean Air Act that case-by-case revisions to emission limitations in the State Implementation Plans were appropriate as long as ambient standards are met. While that position was initially rejected by the lower courts, it has recently been reestablished, in principle, by the Supreme Court. *Compact e.g., NRDC* v. *EPA*, 489 F.2d 390 (5th Cir. 1974) with *Train* v. *NRDC*, 43 U.S.L.W. 4467, 7 ERC 1735 (U.S. Apr. 16, 1975).

[19] *E.g.*, 39 Fed. Reg. 36187 (1974).

[20] *E.g.*, 40 C.F.R. § 423.12(a), 39 Fed. Reg. 36199 (1974).

[21] Cf. Brief for Respondent at 43–44, 47, *NRDC* v. *EPA*, No. 74–1258 (2d Cir., argued Apr. 25, 1975).

[22] See 39 Fed. Reg. 28926–27, 30073 (1974) for an opinion of EPA's General Counsel explaining that costs and other economic factors cannot be considered under the flexibility provision.

[23] For a fuller development of this question, which is also involved in the litigation referred to in the note on page 2, see Brief for Allegheny Power System, Inc., *et al.* as Amici Curiae, *E. I. du Pont de Nemours & Co.* v. *Train*, No. 74–1261 (4th Cir., filed Mar. 5, 1974) and Brief for Petitioners, *Appalachian Power Co.* v. *Train*, No. 74–2096 (4th Cir., filed Oct. 2, 1974).

[24] Supplementary control systems are systems that limit the rate of pollutant emissions during periods when meteorological conditions conducive to ground-level concentrations in excess of national standards are anticipated. The limitation is observed by switching to a fuel with lower sulfur content or reducing station generation.

[25] Model studies that provide a quantitative estimate of the advantages of SCS use are found at 8–9 in the report cited *supra* in note, p. 2.

[26] See *id.* at 8 and the report entitled *Discussion of Benefits and Risks Associated With the Use of SCS in the National Mix of Sulfur Oxide Control Strategies*, prepared by Environmental Research and Technology, Inc., cited there.

[27] *Id.* at 9.

The EPA prohibition on use of SCS alone will cost the utility industry about $80 million by 1980, with little or no social benefit since use of SCS would ensure that National Ambient Air Quality Standards were continuously met in any case.[28]

If EPA's desire to avoid use of supplemental controls and tall stacks is premised on putative sulfate effects on public health, EPA should move to regulate sulfates directly, by promulgating sulfate ambient air quality standards if the evidence warrants.[29] It should not use the backdoor approach of legally indefensible restrictions on otherwise appropriate types of sulfur oxide controls.

5. The Federal-State division of responsibility

EPA has, in many cases, not respected the complex and delicate division of authority Congress established between itself and the states. It has, first, been said to have subverted that balance on occasion by imposing its will under threat of cuts in grants to the state in question. Second, by its SIP "guidelines" and, by such positions as that favoring "nationally uniform effluent limitations," it has improperly pre-empted intended state discretion in the formulation of the Act's requirements. Third, it has not yet adequately defined the procedural relationship between itself and the states as the states exercise their delegated functions. This had led to confusion and litigation in the past[30] and seems to me likely to do so again in the future.

6. EPA's flawed rulemaking process

EPA is charged by Congress with elaborating some exceedingly vague and ambiguous statutory tests—yet as noted earlier literally billions of dollars, basic elements of national supply and demand for energy and the health of our national economy turn of EPA rulemakings. These rulemakings normally must deal with highly complex technical issues, many at the very frontiers of current technological and scientific understanding.[31]

EPA has, in my judgment, taken various unwise or mistaken rulemaking actions based on inadequate or incomplete technical bases.[32] Perhaps. the most expensive such example is the "SIP Overkill" embedded in so many State Implementation Plans. For reasons largely of haste and administrative convenience, emission limitations in SIP's were set by the states, with EPA's encouragement, by use of very conservative methodologies—thus in many cases they are much more stringent than necessary to meet ambient air quality standards. EPA itself, after Congress required that it reassess SIP's, concluded in its May 7, 1975 Report to Congress under § 9 of the Energy Supply and Environmental Coordination Act of 1974 (ESECA), at 16, that "[s]tudies performed by EPA subsequent to the adoption of state sulfur regulations identified approximately 110 million tons of coal [compared to 392 million tons used by electric utilities in 1974] which the SIPs would preclude but which could continue to be used without violating health-related ambient air quality standards." These EPA findings have been confirmed by utility industry studies that found, with model studies, that over half of a 100 plant sample studied could use fuel with a sulfur content higher than that prescribed in the SIP without causing violations of the ambient standards.[33] The *annual* consumer cost in 1980 of "SIP Overkill" has been estimated, in the same study, as $3.6 billion; the capital cost by 1980 at over $8 billion.[34]

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[28] *Id.*

[29] A substantial majority of the scientific community regard present scientific data as too meager to support immediate EPA promulgation of sulfates standards. The consensus of the scientific community is that it will take five to ten years to collect and analyze the additional data needed to know which kinds of sulfates and what levels of such sulfates may threaten human health. Indeed, the massive research effort needed may show sulfates are primarily an indicator, not a cause, of adverse health effects and that it is nitrates or some other pollutants that are the real cause. A by-product of the monitoring required for SCS systems is that it will create a much broader information gathering network during the sulfates study period. Even if subsequent research proves that one or more sulfates are major contributors to adverse health effects, the matter will not be settled, for it is not known at present whether the major source of the locally occurring sulfates that are candidates for this classification is multiple power plant emissions or area sources. *Id.* at 19A–19B.

[30] *E.g.* Appalachian Power Co. v. EPA, 401 F.2d 495 (4th Cir. 1974); Buckeye Power Inc. v. EPA, 481 F.2d 162 (6th Cir. 1973).

[31] *E.g.*, Ethyl Corporation v. EPA, 7 ERC 1353 (D.C. Cir. Jan. 28, 1975), *vacated and appeal for rehearing en banc granted*, 7 ERC 1687 (March 17, 1975).

[32] See note at 9 *supra.*

[33] See page 6 of the report cited *supra* in note, p. 2.

[34] *Id* at 13, 14, 19A.

While EPA has responded to judicial prodding[35] by moving in some cases to open up its rulemaking process and better articulate the bases of its judgments so that industry and other interested parties may know and challenge its technical premises, these more liberal rulemaking procedures are not, in my judgment, even when granted, an adequate response. They depend for their effectiveness on timely, coordinated, in-depth participation by industry and the public—participation that is all too frequently not forthcoming.[36] I believe that a "blue ribbon panel" (or a series of them) of independent scientists should be appointed to report publicly and in writing on the technical bases of rules proposed to be adopted by EPA, and that EPA should be required, in turn, to explain any deviation by it from the findings of that body. Too often, now, sound scientific judgment seems to be subordinated within the Agency to wishful thinking.

7. NPDES problems

It is my belief that in the press of efforts to issue permits under the Water Act too little care is being devoted, in many cases, to policing up important details. Let me illustrate. I can do little more than catalogue some of the problems here, without elaboration and largely without proposed solution.

There are some significant substantive issues, not yet finally dealt with, where prompt EPA action is needed to settle the ground rules under which NPDES permits are issued.

First, prompt EPA decision on publication of its § 316(a) Guidance Manual—in, one hopes, a completely rewritten and more pragmatic version—is essential. In the meantime, applicants are being forced inexorably by the deadlines in the § 316(a) regulations to design and submit for EPA review § 316(a) cases or plans of demonstration and study without any coherent and sensible detailed guidance on the applicable requirements and without knowing whether such guidance is "just around the corner." If § 316(a) methodology is to be left for case-by-case common law style development, that should be announced. If guidance is to be forthcoming, it must issue soon. For similar reasons, a prompt decision on § 316(a) guidance is also necessary.

Second, EPA should make clear to the Regional Administrators (RA's) that no permit may contain any effluent limitation not drawn from the guidelines or affirmatively justified on water quality standards grounds.

Third, EPA should abandon its wide-spread habit of requiring compliance with other laws, whether normally enforced by it or not, as a condition in an NPDES permit. Such a requirement may improperly engraft onto those laws the remedial structure of the FWPCA. States, through their § 401(d) power, are also guilty in this regard and EPA should refuse to incorporate as a condition in a § 402 permit any requirements in a § 401 certificate not properly related to water quality.

Fourth, EPA should expressly revise its guidelines to reflect the views of its General Counsel's office that the term "fundamentally different factors" allows a showing of *facts* fundamentally different from those EPA considered. But beyond this, EPA should reverse its position that, in any case, different *economic* facts or factors cannot be considered under this variance provision.

Finally, EPA should act to clarify the nature of the averaging times referred to in its guidelines as well as to establish, perferably by amendment to its regulations, a common calculational scheme for computing the quantity limitations implicit in its guidelines. This is particularly important for "combined streams" and "net limitations" calculations, especially where variable flow or transit-time complications exist. Intelligent advance resolution of these computational problems, while they may not seem important to Washington-level policy-makers, would avoid a lot of grief for those in the trenches and would go a long way to limiting the possibility for arbitrary agency action at the lower levels.

Indeed, until these computational issues are resolved, no one really knows what the quantity restrictions in the guidelines amount to. They are wholly indeterminate until some basis is established for specifying the flow that is to be multiplied times the guideline concentration numbers.

Turning now to procedural issues, there are, first a number of important revisions that need to be made promptly to the NPDES procedural regulations in

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[35] *See e.g.*, International Harvester Co. v. Ruckelshaus, 478 F.2d 615 (D.C. Cir. 1973); Kennecott Copper Corp. v. EPA, 462 F.2d 846 (D.C. Cir. 1972).

[36] The pace and breadth of lawmaking in this field has frequently outrun the endurance of potential participants, even when their interests are, upon reflection, clearly jeopardized.

40 C.F.R. Part 125, as was pointed out in comments solicited by EPA on its July 24 revisions of last year. For example, administrative stays need to be made available where a legal issue is certified to the General Counsel. At present they are available only where an adjudicatory hearing is granted because a material issue of fact exists. In addition, the point of initiation of the time period for requesting an adjudicatory hearing must be clarified and the time period extended to 30 days. And, most importantly, some process must be provided for notice of pending legal determinations by the General Counsel's office, as well as rights of participation, and general publication of the opinions. Many other similar adjustments also need to be made.

Second, EPA regulations do not now adequately address the problem of deferred issues, either as to the extent and mechanics of adjudicatory hearing rights or as to § 509 appeal problems. Difficulties arise because the current NPDES regulations implicitly assume that all issues will be dealt with, as they should in an orderly world, in proper order and before a final permit is issued. But the frantic rush for permit issuance has prevented such orderly consideration in many cases. Deferred issues are the order of the day. They arise under § 304(b), as well as under §§ 316(a) and (b). For example, § 304(b) issues may have been deferred where the RA has chosen not to hear, before the final permit was issued, the case necessary to establish (1) a § 304(b) guideline exemption, (2) a "fundamentally different factors" case, or (3) a net limitations case. In many cases, where chemical treatment equipment must be designed and flows are thus not yet known, § 304(b) quantity limitations cannot now be set and combined waste streams proposals cannot yet be made. Water quality standards compliance determinations have frequently been deferred where more data is needed to assess compliance. Section 316(a) and (b) cases and plans of study have been deferred wholesale, as have been monitoring program design issues, where the details have been left for negotiation. In short, due to the unavoidable haste with which permits are being issued, there are a myriad of deferred issues as to which the rights of the applicant and the RA should be clarified. Clarification will prove even more important in cases where state delegation intervenes and the deferred decisions are left to be made by the state.

Third, the AEC–EPA Proposed Second Memorandum of Understanding shows that EPA has yet to face squarely the need for pre-construction issuance of a final NPDES permit covering all discharges, both construction—and operation—related. This early permit is needed for *all* plants, not just nuclear plants, for the following reasons. First, there may be some construction-related point source discharges that require a permit from the outset of construction (as opposed to rainfall run-off during construction which is an area source problem that ought not to require an NPDES permit). If this is true, it is more efficient to deal with all issues, not just the construction-related ones, at the construction stage. In the case of a new source, this may be required by NEPA, in any case, where EPA issues the permit (and indeed is done under NEPA at this stage by the AEC, to whom EPA should defer as lead agency in the case of a nuclear plant). It would, in the case of both "new" and "existing" sources, avoid the duplication of making a preliminary determination in addition to the later final permit issuance.

Second, industry needs finality. It needs governmental determinations on which it can rely for design purposes once it begins construction. Third, a § 401 certification must normally be obtained for an AEC construction permit at a nuclear plant and for a Corps "work in navigable waters" permit under the Rivers and Harbors Act for intake and outfall construction at a fossil, as well as a nuclear plant. Where a § 316(a) determination is necessary in order to get a § 401 certificate, it is not at all clear that a "preliminary determination" such as EPA contemplates at a nuclear plant would provide a legally adequate basis for a § 401 certification, even if preliminary determinations were also issued at fossil plants. Clearly, however, a § 316(a) determination pursuant to the issuance of a final pre-construction NPDES permit would suffice. Fourth, if the *Colorado Public Interest* case is not reversed,[37] a pre-construction NPDES licensing by EPA, similar to that of the AEC, is essential if nuclear plant construction is to continue to enjoy the early guidance it now gets from AEC on radiological issues. For these and other reasons, EPA should move immediately to provide procedures for pre-construction NPDES licensing.

Let me turn, finally, to an NPDES issue that cuts across all of the others—the role of the states again. Even if we straighten out the problems of FWPCA imple-

[37] Colorado Public Interest Research Group v. Train, 507 F.2d 743 (10th Cir. 1974).

mentation at the federal level, we still must cope with the complicating factor of potentially disparate implementation by the 50 states.

Substantive uniformity under FWPCA will soon evaporate unless some mechanism is developed to make legal determinations by the EPA General Counsel available to applicants for a state-issued permit, to make such legal opinions binding on the states as well as the RA's, and to make federal appellate review of state-issued permits available under § 509, and, one hopes, exclusive. Perhaps this could best be done through the EPA's permit review power under § 402(d)(2)(B), thus avoiding any "unfair, retroactive application" claims, because of unilateral EPA modification of delegation agreements from states that have already received delegation.

Procedural uniformity among NPDES states has already been largely jettisoned since EPA, unwisely in my judgment, did not try to insure that the functional equivalent of its own NPDES adjudicatory hearings and procedures were available at the state level. Note also, for example, that the administrative stay mechanism available at EPA where an adjudicatory hearing is granted is not federally mandated at the state level, either as to § 401 certificates or § 402 permits. The "preliminary determination" mechanism in the AEC–EPA Proposed Memorandum of Understanding is also not made binding on the states.

Third, neither EPA's own procedural regulations nor those applicable to the states directly address whether or how a permit process begun under the first should be continued under the second when delegation occurs, in midstream, as is frequently happening. To my knowledge, these problems are being worked out on an *ad hoc* basis through the individual delegation agreements with the states, the normal rule being that state procedures take over on delegation except where EPA has granted adjudicatory hearing requests, in which case the federal procedure continues to apply.

The problem of state NPDES participation has, in my judgment, been a stepchild from the start. Almost everyone has focused on the main-stream NPDES issues involving EPA. Unless EPA moves quickly, however, it will find that just when it succeeds in working out the main substantive and procedural bugs in the NPDES system at the federal level, it loses control through state-created fragmentation as the delegation process grinds on.

C. IN CONCLUSION

While it may sound, from this litany of complaints, that I do not believe EPA capable of any wise and useful action, that is not the case. As I noted earlier, the agency is working hard and honestly to carry out some very difficult congressional mandates under impossible congressional deadlines.

What my comments and those of my colleagues demonstrate, I believe, is that:

(1) EPA, though sincere, can be wrong.

(2) Its errors can be reduced if it will force itself to:

(a) Set rules where rules are needed, apply those rules flexibly once set and abjure "under-the-table" policy-making in the absence of rules;

(b) Treat scientific and technological fact (or the lack of it in some cases) objectively;

(c) Weigh carefully, before acting, the total social costs and benefits of its decisions and of alternatives to them, within the context of the substantive mandates of its organic legislation;

(d) Articulate publicly and carefully the bases for its decisions; and

(e) Ensure that its regional officials conform to those decisions.

(3) The Congress has not given EPA the sort of careful and precise but "efficient" statutory guidance that EPA and the public have a right to expect where such fundamentally important social issues are committed to the administrative process for solution.

(4) The Congress has compounded the problem by imposing rigid, unrealistic deadlines on EPA and by requiring immediate challenge and litigation of the administrative output.

Finally, I must note that Congress and the states have been passing environmental laws with great abandon—federal and state NEPA's; laws affecting air pollution, water pollution, pesticides, radiation, and noise; laws relating to coastal zone management, land use, and energy policy. These laws have proliferated into such a crazy-guilt of overlapping and conflicting jurisdictions

and requirements that the private sector is beginning to feel like Gulliver in the hands of the Lilliputians. I do not argue that tough, fairminded environmental controls are not proper—indeed long overdue. What is required now, however, is a statesmanlike effort by the Congress and the state legislatures to untangle the present mess and recodify, with careful craftsmanship, environmental control requirements into clear, simple jurisdictions and requirements. This, more than anything else, will foster faith in the efficacy of the administrative process for solving environmental problems. Until Congress and the state legislatures get their own houses in order, however, it is very difficult, if not impossible, for anyone downstream of them in the law making and law applying process to do so, to the severe detriment of the public interest.

[Attachment to testimony of Turner T. Smith, Jr.]

FWPCA Requires Flexible Implementation

A. THE ACT REQUIRES "GUIDELINES" FOR EXISTING SOURCES—NOT NATIONALLY UNIFORM EFFLUENT LIMITATION REGULATIONS

Congress carefully established, in the three keystone provisions of the Water Act—§§ 301(b), 304(b), and 402—an administrative process in which the 1977 and 1983 standards are to be particularized in two stages: the first affording the full benefits of rulemaking through promulgation of presumptively applicable § 304(b) guidelines, the second involving the equally vital flexibility to "fine-tune" the standards through case-by-case application as effluent limitations are actually set in permits.

Section 304(b) directs the Administrator during the first, and rulemaking, step in that process to publish "regulations, providing guidelines," expressly "[f]or the purpose of adopting or revising effluent limitations. . . ." During the second, case-by-case step, permit grantors are instructed by § 402 to "prescribe conditions" in discharge permits to ensure compliance with the "applicable requirements" under § 301, as elaborated in the regulations setting out the § 304(b) guidelines. Through these two steps the substantive standards of § 301(b) are translated into particularized effluent limitations by weighing the numerous factors determinative of the best technology for each point source.

The guidelines must elaborate the terse substantive statutory standards and may include a single-value numerical limitation for each industrial class, category or subcategory. Subcategorization should occur to the extent feasible. The numerical limitations in the guidelines are presumptively applicable, but not absolutely binding. They are to be applied as effluent limitations in permit conditions unless the permit grantor, or any party, can show that, on the facts of the case at hand, some other limitation more appropriately fulfills the Act's applicable substantive mandate.

Provisions of FWPCA other than §§ 301(b), 304(b) and 402—particularly those reflecting the careful division of responsibility between EPA and the states—further implement congressional desire for this two-stage regulatory process.[38] These provisions also show that Congress expressly called for national

[38] The distinct functional roles assigned to permits and to guidelines are reflected in FWPCA as follows: (1) provisions indicating that effluent limitations are to be set in permits, including the different review periods of § 301(d) (five-year review of effluent limitations) and § 304(b) (annual review of § 304(b) guidelines); § 595(b)'s requirement of prior notice to ES&WQIAC only as to § 304(b) guidelines and §§ 306 and 307 standard promulgation, but not as to § 301(b) limitation setting; the contrast between EPA's authority under §§ 308((a) and 509(a)(2), respectively, and § 316(a)'s reference to "effluent limitation[s] proposed," meaning proposed in the permit; (2) the provision giving the Administrator authority to veto a state-issued permit as outside the guidelines (§ 402(d)); (3) provisions emphasizing the states' role as permit grantors (§§ 101(b), 402(b), 502(11); (4) provisions stressing the need for public participation at the permit stage and requiring notice and opportunity for public hearing (including §§ 208(b), and 402(a)(1), (b)(2), (b)(3) and (c)); (5) the provision obligating the permit grantor to coordinate FWPCA requirements with those of public health agencies (§ 514); and (6) the provisions showing that Congress intended guidelines to provide information and guidance for subsequent administrative actions (*e.g.*, §§ 304(e), (f), (h), 318, 403(c) and 4004(b)).

standards where it wanted them.[39] Indicatively, there is *no* statutory language that authorizes promulgation of rigidly uniform, nationwide effluent limitations.[40]

Like the statutory text, the Act's legislative history indicates Congress' two-stage intent.[41] To ensure that like cases are treated alike, the Administrator is to be as precise as possible in his guidelines, and the states as permit-grantors are to act within those guidelines, subject only to any overriding demands of the FWPCA's substantive requirements. As with the statutory language, there is no legislative history authorizing regulations that set Procrustean effluent limitations.

Congress chose the guidelines process because it affords the advantages of rulemaking without sacrificing the flexibility necessary to ensure application of the best control measures to existing plants in disparate cases. To ensure consistency, the guidelines are presumptively applicable, but their effluent reduction levels are not absolutely binding. Congress wanted "similar point sources with similar characteristics" to meet "similar effluent limitations."[42] It did not intend dissimilar point sources to be strapped with identical limitations in the name of mindless uniformity. The Conferees' call for effluent limitations "as uniform as possible" recognizes that differences do exist and must be accommodated if the FWPCA's commands are to be fulfilled.[43] The permit grantor must heed any material factual differences and make the adjustments warranted by the circumstances in particular cases, thus avoiding the imposition of inappropriate limitations.

It is only through this two phase process that EPA could adequately implement the Water Act. Consider, first, the scope of the administrative task facing EPA (and as delegation occurs, the states) in regulating just industrial sources under the Act. Involved here are 68 major classes and categories of some 30,000 industrial point sources.[45] The number of discrete subcategories which EPA has established, and which do not purport to account for all variability, is staggering. For example, the major classes and categories which EPA has designated as

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[39] *E.g.*, FWPCA §§ 306(b) (new sources), 307(a) (toxic pollutants), 307(b) (pretreatment standards), 33 U.S.C. §§ 1316(b), 1317(a), (b). All these provisions prescribe procedures and schedules for promulgation of the national standards, fix times for them to take effect, and make them independently enforceable apart from § 402 permits. Section 301(b), in sharp contrast, contains none of these elements.

[40] Section 501(a), which gives the Administrator general authority to prescribe "such regulations as are necessary to carry out his functions under this Act," does not authorize effluent limitations by regulation. Such general provisions can only be invoked "consistently with the provisions and purposes of the legislation." Public Serv. Comm'n *v.* FPC, 327 F.2d 893, 896–97 (D.C. Cir. 1964). FWPCA manifests Congress' intent to set up a two-stage process for the particularization of effluent limitations and, by its terms, directs the Administrator to use his rulemaking authority to provide guidelines in aid of that process. § 304(b), 33 U.S.C. § 1314(b). The Act's scheme neither allows nor accommodates use of rulemaking authority to set effluent limitations—those limitations are to be set as each permit is issued. *See* Senate Report 51, 2 Leg. Hist. 1469. Provisions such as § 501(a), in short, "merely augment existing powers conferred upon the agency by Congress, they do not confer independent authority to act." New England Power Co. *v.* FPC, 467 F. 2d 425, 430–31 (D.C. Cir. 1972), *aff'd.* 415 U.S. 345 (1974) (footnote omitted) (general rulemaking authority does not support regulations assessing administrative costs under one part of Natural Gas and Federal Power Acts where such authority is expressly granted in other parts and omitted in the parts in question).

[41] *See, e.g.*, Senate Report 44, 50, 51 reprinted in Senate Comm. on Public Works, 93d Cong., 1st Sess., 2 A Legislative History of the Water Pollution Control Act Amendments of 1972 at 1462, 1468, 1469 (Comm. Print 1973) (hereafter cited as Leg. Hist.).

[42] *See, e.g.*, Conference Report 126, 1 Leg. Hist. 309.

[43] Conference Report 126, 1 Leg. Hist. 309.

[44] To the extent that Congress feared industrial "forum shopping" if effluent limitations were not uniform, there are two short answers. First, an existing plant cannot change its location without becoming a new plant subject to more stringent new source standards. *See* 118 Cong. Rec. 10215 (1972), 1 Leg. Hist. 379 (remarks of Rep. Clausen); *id.* 10663, 1 Leg. Hist. 579–80 (remarks of Rep. Roe). Second, as to the electric industry, a utility normally has a public service obligation to serve a discrete geographical area. It cannot terminate service or close an uneconomic plant unless it makes adequate provision for replacement capacity. Thus, whatever may be the case in other industries, relocating utility industry power plants from one region to another is not a practical alternative.

[45] The Act in § 306(b) listed 27 industrial categories which the Administrator was expected to "concentrate on, but not be limited to" in developing effluent limitation guidelines under § 304(b). House Report 107, 1 Leg. Hist. 794. But a United States District Court found that the Act requires "comprehensive section 304(b)(1)(A) guidelines" covering all industrial categories. Accordingly, by Order of November 27, 1974 the list was expanded from the 27 industrial categories of § 306(b) to include 68 categories which the court found "necessary to provide comprehensive coverage of all point source discharges." NRDC v. Train, Civ. No. 1609–73 (D.D.C. Nov. 27, 1973) (Green, J.), *appeal docketed*, No. 74–1433, D.C. Cir., Apr. 18, 1974. As of last Fall, over 29,937 permit applications had been filed.

"Group I, Phase I" industries include 203 subcategories.[46] And since EPA must simultaneously develop "best practicable" and "best available" guidelines for each subcategory, these 30 Group I, Phase I classes and categories require development of 406 separate guidelines. And there are another 38 major classes and categories, which will include an unknown number of subcategories.

Developing effluent guidelines for each subcategory requires detailed, extensive study of waste stream characteristics and treatment capabilities typical in that subcategory, as well as full technical and economic analyses to provide the technical and economic bases for the regulations. In this regard, the § 304(b) factors provide a host of relevant grounds for distinguishing among plants. The material differences among facilities in many of the existing subcategories effectively preclude development of appropriate "nationwide, uniform effluent limitations" for the present subcategories, or definition of a sufficient number of refined subcategories.[47]

Of note, second, is the magnitude of potential error. Inflexible limitations based on hasty analysis could prove enormously costly. Inappropriate limitations, mechanically and universally applied to all plants in a subcategory, could result in wasteful expenditures of literally billions of dollars, adverse environmental effects, and unnecessary consumption of scarce energy resources.[48] Congress was aware that the costs of control, though uncertain, would be enormous. Thus it required a careful weighing of economic, environmental and energy costs both as the guidelines are formulated and as the limitations are set.

EPA's supporting analyses for its water pollution requirements have been conducted necessarily in the aggregate, looking to typical plants and national-scale problems posed by selected technologies. State or regional disparities have been largely ignored. Optimal use of resources and avoidance of gross errors, accordingly, require that permit grantors have the flexibility to depart from guideline numbers to the extent that the facts of a particular case warrant such a departure.[49] Otherwise, predetermined effluent limitations or control technologies may be imposed in circumstances that make them infeasible or environmentally counterproductive.

Of note, third, are the tight statutory deadlines imposed by Congress. The legislators provided only one year for the development and publication of effluent guidelines.[50] And they then required that permits establishing effluent limitations be issued by last December 31, 1974.[51] Even if the task were thought possible given unlimited time, EPA could not possibly have defined the subcategories necessary to account for all plant variability within the single year allotted to guideline development. In light of the single year for their development, the guidelines' particularization of the Act's standards is obviously to be for relatively gross groupings. Publishing the guidelines within even the two-year schedule established in *NRDC* v. *Train* wholly precludes the detailed subcategorization NRDC envisages.

Faced with the task of designing "a detailed, comprehensive, effective"[53] regulatory program to carry out its water pollution control objectives quickly and efficiently, Congress chose a careful mix of general rules and case-by-case determinations, involving a partnership between federal and state governments. The FWPCA's two-stage administrative process thus enjoys the advantages of

[46] In some industries the number of subcategories is extensive. The inorganic chemicals category, for example, is comprised of 22 subcategories.

[47] The tremendously varying factual situations among power plants in the electric utility industry alone demand the fine-tuning mechanism established in FWPCA if EPA is to hew to the Act's substantive commands and to achieve real, as opposed to spurious, uniformity of treatment. For example, engineering problems peculiar to specific sites or plants can cause the capital costs of backfitting closed-cycle cooling to vary from case-to-case at least 900%, from $9/kw to $81/kw. See Brief for Petitioners, Appalachian Power Co. v. Train, No. 74-2096 (4th Cir., filed Oct. 2, 1974) at 44.

[48] These ills are among those Congress sought to avoid by specifying them for special consideration in § 304(b), 33 U.S.C. § 1314(b). See testimony at 2 for estimates of the cost of EPA's air and water programs for the electric utility industry.

[49] If, for example, engineering aspects of the control or treatment technology on which the guidelines were based are incompatible with a plant's processes, the permit grantor must modify the effluent limitations applicable to the plant. Similarly, a particular treatment method may be ineffective or counterproductive in an inhospitable climate.

[50] § 304(b), 33 U.S.C. § 1314(b).

[51] § 402(k), 33 U.S.C. § 1342(k). This subsection provided, in effect, a moratorium until December 31, 1974, on enforcement action and citizen suits against discharges without a permit.

[53] 118 Cong. Rec. H. 9119 (daily ed. Oct. 4, 1972), 1 Leg. Hist. 235.

rulemaking without sacrificing the precision required to satisfy the Act's mandate that the *best* controls be applied in each case.

The promulgation of guidelines ensures technologically-informed decisions by the permit grantor and indicates attainable levels of effluent reduction. In the development of the guidelines, characteristics common to plants in a subcategory can be analyzed through the gathering of generic information and the treatment of generic issues. The technical expertise available to the Agency can be brought to bear on these matters to resolve common issues and provide technical aid otherwise unavailable to the permit grantor. If available information is sufficient, the guidelines may contain numerical limitations developed by balancing the § 304(b) factors, and which are presumptively applicable.

Aided by the guidelines, the permit grantor brings to bear his greater familiarity with local conditions in analyzing the facts of each case to determine whether they affect the balance struck in the guidelines. If so, he then makes any adjustments necessary to ensure that § 301(b)'s substantive requirements are met by effluent limitations applied in the particular case.

Like the interplay between guidelines and limitations the federal-state partnership reflects congressional desire for efficient use of administrative resources in implementing the Act. Congress consciously selected an administrative regime which would fully utilize available resources of the federal government and over fifty state agencies[53] in the herculean task of establishing appropriate limitations for all industrial point sources within the Act's stringent deadlines.

Against this background, EPA choice of "national uniformity" is critically defective because it shackles EPA to rulemaking alone. It denies to the FWPCA's administrators the benefits of any case-by-case particularization of the statutory standards, wasting the administrative resources and skills built up in the fifty states, contrary of the intent of Congress. Virtually all variability among plants would have to be accounted for by rules setting inflexible effluent limitations, reducing the states to mechanical application of given numbers without regard to the facts at hand. Unique or novel circumstances encountered in the Act's administration would necessitate EPA's promulgating revised regulations, at great cost to the faithful, speedy implementation of the Act's substantive requirements.[54] Denying EPA the flexibility to make case-by-case adjustments would impede the Act's administration just as effectively as would denying the Agency the power to make substantive rules.

B. TO SATISFY FWPCA IN PARTICULAR CASES EPA MUST ADOPT A MEANINGFUL WAIVER MECHANISM

Independently of FWPCA's call for existing-source guidelines, EPA must make some provision for adjusting its general rules, both for existing and for new sources, in special circumstances. The Administrator's authority to publish rules defining best technology for a range of situations does not relieve him of the duty to determine what is best in particular cases. *See WAIT Radio* v. *FCC*, 418 F. 2d 1153, 1157 (D.C. Cir. 1969).[55] Indeed, the congressional intent that FWPCA's substantive requirements be carefully implemented cannot be effectively honored without such a waiver mechanism. *Cf. United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, 201–202 (1956).

The Court in *WAIT* articulated the governing principle in these terms:

> The agency's discretion to proceed in difficult areas through general rules is intimately linked to the existence of a safety valve procedure for consideration of an application for exemption based on special circumstances.[56]

The court noted that "a system where regulations are maintained inflexibly without any procedure for waiver poses legal difficulties," and observed, that, although a general rule may be valid under the pertinent statutory standards,

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[53] *See* § 502(3), 33 U.S.C. § 1362(3).

[54] Even as of last Fall, EPA has had to propose or publish regulations revising 12 of the 27 guideline regulations it has published. Understandably, this process has impeded the development of guidelines for additional industries. Defendants Memorandum in Support of Motion for Modification of Order at 5, NRDC v. Train, *supra*.

[55] *Cf.* United States v. Allegheny-Ludlum Steel Corp, 406 U.S. 742, 755 (1972) (an agency's authority to proceed in a complex area "by means of rules of general application entails a concommitant authority to provide exemption procedures in order to allow for special circumstances"); Permian Basin Area Rate Cases, 390 U.S. 747, 784–787 (1968).

[56] 481 F. 2d at 1157; *accord*, United States v. Storer Broadcasting Co., 351 U.S. 192, 201–202 (1956); *see* Amoco Oil Co. v. EPA, 501 F.2d 722, 748–49 (D.C. Cir. 1974); Essex Chem. Corp. v. Ruckelshaus, 486 F. 2d 427, 433 (D.C. Cir. 1973); Portland Cement Ass'n v. Ruckelshaus, 486 F. 2d 375, 399 (D.C. Cir. 1973).

its application in particular instances may not be.[57] A waiver provision allows such instances to be identified and appropriate adjustments to be made, so that the statutory mandate can be fulfilled in particular cases. For that reason, "provision for waiver may have a pivotal importance in sustaining the system of administration by general rule." [58]

[Whereupon, at 12 noon the subcommittee recessed, to reconvene at 2 p.m.]

AFTERNOON SESSION

Senator Abourezk. The hearings will reconvene.

TESTIMONY OF ANTHONY Z. ROISMAN, ROISMAN, KESSLER, AND CASHDAN

Mr. Roisman. My name is Anthony Z. Roisman. I am an attorney at the law firm of Roisman, Kessler, and Cashdan. We appear here today on behalf of our client, the New England Coalition on Nuclear Pollution.

The New England Coalition is made up of representatives of the six New England States, and has as its stated objective the development of a rational energy policy in New England; in particular, the discontinuance of a reliance on nuclear power, and instead a shift to more energy conservation and less detrimental to the environment types of energy, such as solar energy, wind power, and similar types of energy options.

Our interest in the hearings you are holding today relates to our intervention before the Nuclear Regulatory Commission in the proceeding to issue a construction permit for two 1,100-megawatt nuclear powerplants on the coast of New Hampshire at Seabrook, N.H. In the course of that hearing, the applicants sought from the Environmental Protection Agency an exemption from the requirement that it must have cooling towers in the plant. The principal reason for seeking exemption was that if it had to build cooling towers, it would have to clearly have chosen an alternate site, and conceivably an alternate method of generating electricity.

The company followed appropriate procedures, and filed with EPA a request for an exemption under section 316(a), and EPA, to the best of our knowledge, followed the appropriate procedure, filed a notice in the Federal Register that said an application had been filed, and notice of public hearing. That hearing was held on January 30, 1975.

The hearing was not an adjudicatory hearing and that was consistent with the regulations. The hearing instead looked in a legislative context at the applicant's evidence that he did not need cooling towers, and that his proposed intake structure location was appropriate.

On March 18, the Acting Regional Administrator issued a final determination, stating that under certain conditions, the company could build its nuclear powerplants at those sites without cooling towers, and disapproving the company's proposed location for the intake structure, but allowing them 3 years to submit data and to have a hearing at a subsequent time on the proper location for their intake structure. It is at that point that our story really begins, and this is not a

[57] WAIT Radio v. FCC, 418 F.2d at 1157.
[58] 418 F.2d at 1158.

story, I should add, of greed or corruption. It is, much more sadly, a story of stupidity and insensitivity on the part of the Environmental Protection Agency.

Beginning on March 18, what occurred is that the Environmental Protection Agency began to hold a series of meetings with the applicant, unbeknownst to us and any members of the public. And the avowed purpose of those meetings was to modify, alter, or change the original determination issued on March 18. That is in conflict with this statement which appears in the final determination, as published on March 18, 1975. At the end, it states:

> These determinations may be modified, suspended, or revoked for the cause, after notice and opportunity for a public hearing, and subject to appeal in accordance with 40 CFR, section 125.36, or other appropriate regulations.

So, there was a method by which the company could, if it chose, seek a modification of the proposed final determination. Instead, the company chose to follow an entirely different route, and I now would like to quote from testimony—excuse me; from the statement made by the counsel for the company, and the company involved is the Public Service Co. of New Hampshire, that was made before the Nuclear Regulatory Commission in hearings that the Nuclear Regulatory Commission was having on this plant on April 16, 1975, and I quote—the speaker is Mr. John Ritsher, partner in the law firm of Ropes and Gray in Boston.

He is referring to the final determination on March 18:

> As soon as they were issued the applicant contacted EPA, because there were a few provisions in here which were ambiguous in their language. And there was one provision, with respect to the precise location of the intake, which from the applicant's point of view was totally unfeasible as written. There was a discussion 2 days after the stocktaking of the position, in which representatives of the State of New Hampshire and of the applicant met with representatives of EPA, and discussed this document, and attempted to analyze the paragraphs we felt were ambiguous, to see if it was possible to make some clarifying changes to those sections.
>
> Some agreement was reached with EPA as to the interpretation of those paragraphs at that time. There had been further meetings of the applicant and New Hampshire personnel with biologists from the Narragansett Laboratory, were instrumental in drafting some of the provisions of this document, to further discuss the basis for the decision with respect to moving the intake; and there was a subsequent meeting with representatives of the applicant and EPA personnel in Boston, at which we discussed a counterproposal the applicant was making for the location of the intake, because we felt that it was necessary to reach as promptly as possible a definitive location for the intake, so that this proceeding would be able to move forward.
>
> It was my understanding from those conferences that EPA intended to issue a new document which would clarify the ambiguous paragraphs of these determinations, and would also indicate its essential agreement with a new location for the intake proposed by the applicant; and that it was acceptable to EPA, subject to obtaining some validating data to indicate that position does not create any adverse environmental impacts other than the impacts of the present location.

Every one of those meetings was unbeknownst to any member of the public until this statement was made on April 16, 1975. It has been EPA's position that it had a perfect right to hold the meetings, to make the commitments to change the final determinations as issued by its hearing examiner on March 18, and to make a commitment to locate the intake structure at a different place without public knowledge, without public hearings—without any public filings by the applicant.

It is important to see just what took place in those meetings to understand some of the motivations, because EPA has in fact done the very things that the counsel for Ropes and Gray indicated they would do, pursuant to those secret meetings. Perhaps the most significant of all the meetings was the one that was held on April 11, 1975, between EPA and the Governor of the State of New Hampshire. In a memorandum dated April 22, 1975, Jeffrey Miller, who was the director of the Enforcement Division for EPA region 1, states, with regard to that meeting, "The Governor expressed his general satisfaction that the procedure is underway. He stated he wanted to see dirt fly and jobs created by July. JASM"—referring to one of the representatives at the meeting—"said he would be finished by July 1"—this is in paren now—"This date seems a bit premature in view of the work required, although it could substantially be done in July if all those adopt complications."

"The Governor said he wanted no excuses that if EPA got off schedule he would sue EPA, or bring as much White House or other political pressure to bear on it as possible."

Now, that is the kind of meeting which EPA was holding, and precisely the kind of meeting we think the public should have an opportunity to attend. In fact, assuming that the representatives of EPA wanted to avoid exactly that kind of pressure, the best way for them to avoid it was to have had a member of the public there to tell the Governor in no uncertain terms what we have told him since we learned of the meeting; that he had no right to bring political pressure on EPA to attempt to force them to make a decision that was inconsistent with the facts.

Senator Abourezk. Is there any law or regulation that would prevent that kind of thing from happening?

Mr. Roisman. In my judgment, there is. To begin with, the regulations under which EPA operates provide that if a party wants to change a determination that has been made, they must take an appeal and file appropriate papers. The determination in question here has that as the caveat at the end, that if you are not satisfied with the document, you may appeal or seek a modification after notice and opportunity for a hearing.

So, I do not think there is any doubt that EPA should never have considered the applicant's suggestions informally that it modify the determinations that it had previously made.

Senator Abourezk. Should there be further statutory clarification, however, to make sure that there is notice and that they are precisely aware that they cannot do that kind of thing?

Mr. Roisman. I wish I could tell you no, because I think the statute is clear. But there seems to be some doubt here about what I think is clear and what EPA thinks is clear. So I do not think that it would be remiss at all for an additional clarifying amendment to the Federal Water Pollution Control Act Amendments of 1972 to state explicitly that EPA, one, should not conduct meetings without giving prior public notice of the meeting and an opportunity for people to attend.

Senator Abourezk. I agree with you.

There is another problem that arises—ex parte contacts. How would you handle that problem?

Mr. Roisman. I think there are two things. It is rare that an agency will hold a meeting at which people from outside the agency attend without somebody having called in advance and saying, "Hey, we are coming over." Usually, there is an arranged meeting if anything substantive is going to happen. The place where you get this sort of informal discussion, where someone picks up the phone and they call a guy and say, "Hey, I want to talk to you about something"—I think the phone calls are a problem. You cannot say, "I am sorry, you will have to give notice of the existence of this phone call before you can keep talking." But I think you can cover that by making sure that a memorandum, which ought to be made by a sound, intelligent person in a Federal agency making any phone call anyway, is made, put in the record. And, if parties have previously asked for a copy, that they be sent a copy, just as though it were a filing, or made of the case.

If the Public Service Co. of New Hampshire were to file with EPA a request, EPA would put it in the public docket, and also make it available to any parties who are on the service list. They could do the same thing with memorandums, phone calls. If there should be a meeting that is held impromptu, without having been previously known that it was going to occur, they could make minutes of that meeting.

The thing that is important is that EPA, if it is holding a meeting or having a phone conversation without anybody knowing about it in advance, should be scrupulous about making sure its notes are fairly extensive. At a meeting that there has been prior notice of, and people can attend, then it is their business to come to the meeting, and they do not have to expect EPA to make a verbatim transcript or anything equivalent to that.

Senator Abourezk. How would you phrase such an amendment to the law that would make a distinction between those meetings which must be noticed prior to the meeting and those in which minutes must be kept?

Mr. Roisman. I would think that the statute should say that the Environmental Protection Agency should, to the fullest extent practicable, hold meetings sufficiently far in the future that they will have an opportunity to advise members of the public of the existence of the meeting. I might say that with regard to this, irrespective of the statutory change, the Nuclear Regulatory Commission and its predecessory, the AEC, with whom I have had most of my administrative experience, have excellent policies by which we receive notice all the time of meetings between companies like Public Service Co. of New Hampshire and the staffs of those agencies. We get those notices when the meeting is going to be very quick by phone. If it is going to take place over a longer period of time, we get it by mail. Sometimes we get it by telegram.

What we get is a real spirit in the Agency, to make sure that we know if it is going to be a meeting, and such a meeting is going to be held. That is the spirit which EPA does not have. In the letter I wrote to Mr. Zener, following a letter that he sent me objecting to the present policy, I suggested that he sit down with the executive director of the legal department of the Nuclear Regulatory Commission, Howard Shapar, and discuss in depth with him the Nuclear Regulatory Commission's procedures with respect to this issue.

Senator Abourezk. I just suggested to the staff that that point be made very strongly in the report that is written on this particular series of hearings. It may not even be necessary to pass regulatory legislation, provided that the report language is following.

Mr. Roisman. Thank you. I think this will materially improve the EPA's present situation. In fact, what is interesting when you ask about whether we need statutory or regulatory changes, is that EPA, one would have thought, already understood this principle. In 40 Code of Federal Register, section 105.2—and this is the section that deals with public participation and water pollution control—that section states, "Participation of the public is to be provided for, encouraged, and assisted to the fullest extent practical, consistent with other requirements of the act and Federal and State government water pollution control activities."

And it goes on to say further, "Conferring with the public after a final agency decision has been made will not meet the requirements of this part. The intent of these regulations is to foster a spirit of openness and a sense of mutual trust between the public and the State and Federal agencies, and efforts to restore and maintain the integrity of the Nation's waters." And I can state to you as a fact, based upon the attitudes of my clients, that represent a substantial number of concerned citizens of New England, that there is no longer any mutual trust between those citizens and EPA region 1 as a result of what has happened there.

In fact, it was on May 16, 1975, that EPA actually amended that earlier determination, by letter written to the applicant, indicating that there will be changes made in the determination that was made as a result of the public hearing. These changes go on for a couple of pages, and I have made them available for the record. Those changes were all made without prior public notice, without any participation in their making, without any Federal Register notice—without any opportunity for a hearing, without following any of EPA's procedures.

It seems to me that kind of a policy is bound to cause the kind of mistrust that is beginning to develop.

The present posture of the EPA proceeding is that EPA is scheduled to hold a hearing, probably in August, on the proposed location for the intake structure. Remember, EPA originally rejected the intake location as improper, and said, you do some studies and come back to us with the data, and we will hold another hearing to determine whether the new location is proper.

But as applicant's counsel, Mr. Ritcher, indicated the applicant wanted EPA to give them a private agreement that they had already approved the site.

EPA apparently has done some of what they wanted and some of what the Governor of New Hampshire wanted; namely, speeding up the decisionmaking process.

According to a letter that was submitted by counsel for the Nuclear Regulatory Commission's staff, to myself, among other people, dated July 15, 1975, EPA is going to hold this hearing in August, even though—and I quote—"as of the time of the meeting, EPA had no position on applicant's proposed intake, and indicated they would most likely take no position during the public hearing."

In short, EPA is proceeding with the hearing although it does not yet know whether or not the proposed intake structure is appropriate.

And what is significant about that is that the regulations indicate that where there is insufficient data available, the proper course of action to be followed by the Agency is to send the application back to the applicant and ask the applicant to review the application. This is in section 122.15(b) of the EPA regulations, which provide that the provisions of section 122.10(b) of this part are applicable in any case in which the Director determines, after reviewing the evidence which the owner or operator proposes to present at the hearing, that sufficient information is likely not to be available upon which to base a knowledgeable determination of whether or not the proposed effluent limitations on the thermal component of the discharge are more stringent than necessary.

Basically, what this regulation is saying is that if the applicant does not submit enough information to make an intelligent decision, then you should not have the hearing at all. Yet EPA, although indicating to the Nuclear Regulatory Commission's counsel that it thinks it had enough information to know what position to take, is nonetheless holding a hearing—and I suggest the reason it is holding a hearing is because the Governor of New Hampshire told them in no uncertain terms that he was going to bring White House pressure to bear—and we have got to remember who it is the regional administrator of region I works for; his boss is the President of the United States who resides in the White House. It is that kind of pressure, those kinds of activities, that I find most objectionable.

Finally, I think perhaps we could get an understanding of the EPA attitude with respect to this by looking at the response that came from the General Counsel to my initial letter objecting to the procedures that we have been talking about today.

In a letter dated May 9, 1975, Mr. Zener makes the following most extraordinary statement: "As you know, your client heretofore sought to meet with EPA on this matter. I would be pleased to do so at a mutually convenient time. I understand that Mr. McGlennon"—he is the administrator for region I—"and his staff are also available to meet with you and discuss any issues relating to the section 316 termination. If you request such a meeting with Mr. McGlennon, I am sure that unless you so request, he will not delay the meeting by requiring prior publication of the notice in the newspaper, nor will he dilute the opportunity for you to present your views by inviting the company to attend. I am sure you will recognize the unworkability of such procedures."

To begin with, we never suggested there be newspaper publications. There has already been a hearing by EPA on this matter, so they know who the interested parties are. A written letter would have been more than adequate to alert the interested members of the public to the conduct of any meeting.

Second, I have never found it an inconvenience to have a meeting that I wanted held delayed by having other people who would be interested in the meeting attend.

And finally, I have yet to attend a meeting in which I was the principal speaker, in which I had anything to say that was diluted because somebody from the other side was present. Much to the contrary; usually I have the naive belief that if they are there, I might persuade them, too.

I do not know what it is Mr. Zener thinks may happen if members of the company are present and members of the public want to speak, but I am concerned he may think that if members of the public are present when the company wants to speak, that the compay may pull a few of its punches. If the company has got anything to say and is afraid to say it in the open, that is all the more reason why the meetings ought to be attended by members of the public.

What is it that EPA can do about this?

First, as I have suggested before, they could go and talk to the Nuclear Regulatory Commission, who does a much, much better job. They have not found any great administrative difficulty in doing it.

Second, what you have suggested, Senator, the availability of memorandums on meetings that are held where they did not have an opportunity to tell members of the public or where they did not know of any interested members of the public, so that someone could go back and look at the files and find out what did the company say to them on that day or why did the Governor want to meet with those people.

Third, I think there needs to be some mechanism established for the Agency to separate the staff of the Agency that deals on a daily basis with applicants and the members of the public. And those people in the Agency, like the regional administration, who are, pursuant to the regulations of the statute, charged with the job of being judges.

What we had here were meetings at which Mr. McGlennon attended and sat in and listened to the presentations made by the applicant. Soon, Mr. McGlennon, under the regulations, would be charged with the responsibility to sit as a judge in an adjudicatory hearing to decide whether the original determinations which were made were proper or not.

I see no sense, nor do I think it very likely to have occurred in any other agency that had some sophistication in this area, that tomorrow's judge becomes today's representative in a secret meeting. That simply is not the way the democratic process works.

I think the committee's suggestion that in its report it would indicate in no uncertain terms that EPA has a different obligation which it should follow would be extremely appropriate.

I would also request that the committee consider writing to EPA and asking that, based upon the documents which I have submitted in the record today, to explain what in the world has been going on with the secret proceedings.

My clients are deeply concerned that an issue of great importance is being handled in, at best, a most cavalier way, and at worst, a way which probably violates their rights under the statute and, conceivably, under the due process clause of the Constitution.

EPA has been unable or unwilling to give us any kind of a definitive answer to the questions: How do they treat the kind of changes that they made in those determinations as mere clarifying changes? How do they explain the fact that the detemination which they modified said by its terms that modification was to occur only after public hearing and as the result of an appeal by the applicant? How do they explain the fact that they are now going to hold a hearing on a proposed new location for the intake structure for this plant even though they do not have enough information to know whether they can make an intelligent decision, and the regulations tell them that in such a case

they should not hold a hearing at all? And finally, how are they going to explain that the regional administrator has not knuckled under to the threat of or conceivably the actual application of White House pressure to get this decision made regardless of whether it is right or wrong, just so the Governor of New Hampshire can see the dirt fly.

I worry that a Governor like the Governor of New Hampshire might very well want to see someone build a heroin factory in the State of New Hampshire if he thought it would employ a lot of people building it.

Seriously, it does not follow that any thing that employs people building is necessarily good. New Hampshire has got an unemployment problem; it has also got an environmental problem, and it ought not to be EPA's job to try to help them solve their employment problem while exacerbating their environmental problems.

Thank you.

Senator Abourezk. Thank you.

Mr. Tobias. In the message of the President which accompanies Reorganization Plan No. 3 of 1970, establishing EPA, much was made of the fact that a single agency in charge with handling environmental programs would be able to coordinate environmental protection efforts then scattered throughout the Federal bureaucracy.

To what extent has this proven to be a correct assumption?

Mr. Roisman. I would not feel that I am competent to address that. As I explained before, my principal substantive interest has been in nuclear matters, which were not transferred. My sole exposure to EPA was this one incursion. I would like to believe it is nothing but an aberration on an otherwise perfect agency record. But I do not have enough knowledge about that agency to know whether it works this way all the time or just only this one instance.

Mr. Tobias. We questioned a panel of private lawyers earlier today about how EPA interacted with other Federal agencies in undertaking and fulfilling its statutory obligations.

For example there is a great deal of interface between NRC and EPA in siting of nuclear powerplants. Can you give us your reaction to how EPA has interacted with NRC in the Seabrook proceeding?

Mr. Roisman. Yes.

I think the Seabrook proceeding is one of those that falls into what we commonly call the transition period. As you know, the guidelines for steam electric powerplants were not issued until the end of 1974. The Seabrook hearing was already in progress, but the regulations applied to the Seabrook plant; thus the applicant was faced immediately with the responsibility of having to get either variance from EPA requirements for cooling towers or, alternatively, having to go ahead with trying to get a license for the plant with cooling towers, with the consequence of economic disadvantages associated with it.

The NRC/EPA agreement is that EPA will make a preliminary determination as to the 316(a) question if requested by an applicant to guide the Nuclear Regulatory Commission hearing board to know what it is the plants really are going to look like and then to be able to evaluate its impact.

I think NRC and EPA in this have acted fairly responsible, in that it would not have been in the public interest to simply have postponed indefinitely a decision on what the Public Service Co. of New

Hampshire asked for. And they have tried to coordinate to hold the hearing on an expedited basis to issue the determination on the expedited basis—which was all done in less than 3 months from when the final regulations came out.

I do not have any complaint about that, although I may not agree with the decisions they made. I do not have any complaint the procedures they follow that could have been guidance for our hearings on environmental matters in the Seabrook proceeding. What they did after that, though, was totally undercut the legality of what they did before. And now, appeals have been filed from the final determination, which technically became final for appeal purposes only on July 10, because of the need to go to the State to get a 401 certificate. That has now been appealed, principally on the procedural ground that EPA modified the original determination improperly.

So, the interface worked all right, but EPA, when acting on its own, so misconstrued its responsibility that it is now subjecting itself to what may end up being a court challenge that will overturn that determination and leave the public service company in New Hampshire back where it was on January 1, 1975, not knowing whether it will have to build a cooling tower on its plant or not. But that I cannot blame on the mechanism for interaction, as such; that worked pretty well. I do not have any gross objections to the way NRC and EPA act. I assume that in the future, companies will go to EPA as soon as they are thinking about building a powerplant if they want a 316(a) exemption, and ask for their approval before they ever submit their application to the Nuclear Regulatory Commission. That could not have happened in our case, but it certainly could happen for license applications that are filed in the future.

I assume EPA will eventually set up a hearing mechanism that will allow those decisions to be made relatively promptly, without too much delay. I think a company needs to know where its regulatory requirements lie as soon as possible so it can make its choices.

Mr. Tobias. You said there is a hearing pertaining to location of the intake scheduled in August.

Mr. Roisman. That is correct.

Mr. Tobias. Is that a 316(b) type of hearing?

Mr. Roisman. That is a good question, and nobody really knows the answer.

The EPA regulations do not explicitly cover procedures with 316(b) certification; they cover only 316(a) exemptions. It has been assumed by everybody that the 316(a) exemption and the 316(b) certification have to happen at the same time because the statement in 316(b) talks about finding the best possible technology to mitigate the consequences of the location, capacity, and design of the intake structure. The capacity of the intake structure relates directly to cooling towers. So, you might have a situation in which a company got exempted under 316(a) because the thermal component was not a problem, but could not get a 316(b) certification because the impingement and entrainment problems associated with intake capacity created a problem in which the only technology that was available to minimize the adverse environmental impact was these cooling towers. So you should probably hold them both together. But the EPA regulations are unclear.

What EPA did was, they said we are not ready to say you have to have cooling towers to deal with your intake problems, but we do know that where you are proposing to put your intake is unacceptable. We do not know where you can put it and be safe, but we will draw a triangle, and if you want to be within that triangle, you come back to us with evidence and we will hold a new hearing, which will be a legislative type of hearing, on your proposed new location for the intake structure.

So, that is the hearing that is going to be held in August.

Mr. Tobias. It seems to me that drawing a triangle in the aquatic area where the intake might possibly be located is a far cry from what is contemplated under the Water Act in terms of what type of intake problems might be experienced. It seems to me that studies of some extended duration, probably during migratory seasons, might be warranted before any type of hearing could be held or a determination could be made.

What is your feeling about that?

Mr. Roisman. That I would like you to be the regional administrator of EPA region I. That is exactly the position we are taking, and that is—I should say EPA, in its original determination said, you come to us in the next 3 years with studies and we will identify proposed locations.

What the company did was, they said, hey, we cannot wait 3 years; we cannot wait 3 months. The Governor said he wants dirt flying next week.

So, what they did was, they took already existing data that they had and tried to patch together enough evidence to establish another location. We think that location has not had enough data on it to make an intelligent decision. We think EPA should have the guts to say to the company, this is not enough information. Instead, they are going ahead and noticing the hearing and get a steamroller going in which there will be a temptation to give it a definitive decision.

I would be concerned with EPA's rejecting the applicant's location on the ground that it was not good for the environment as much as I would be concerned with them accepting it on the grounds that it was good for the environment if they did it without enough information. Either would be wrong. My clients' interest in terms of where that intake is put, is we want it to be put in a place that is environmentally sound and we do not want it to be more expensive, located in a different place, when it does not have to be, because my clients will have to pay the electric rates that that utility would be charging as a result of overbuilding its plant.

So, both sides are concerned, or should be, with finding out the right location. The difference is, the company wants to find out any location now; it does not care whether it is right or wrong, as long as they can build it at that site. They now have put this thing on their time schedule. They want to see dirt flying before the end of 1975. So they are putting pressure on to have a decision made when EPA, it seems to me, should have been telling them just what you said: Let us get some more definitive studies of these alternative locations within the triangle.

Mr. Tobias. You raised another interesting point—how public interest groups such as the one you represent can obtain the funds to

undertake such studies. Does this present real problems? Do you have to rely upon EPA and what studies it does?

Mr. Roisman. Depending upon how much time you have got, I would be glad to address that issue. I will give you a brief summary. And then you can tell me whether you want to hear more.

You have hit on one of my pet subjects. I think the public interest groups cannot adequately participate in EPA or any other agency's process unless they have some financial assistance from the agency or from someplace else. It simply is not going to be possible to get their noneconomic interest sufficiently represented by dollars unless somebody comes and gives them help.

There have been foundations that have done it but they are getting disenchanted because they like to move on to new fields. There have been public contributions. That is what my client operates on, contributions from the general public. But there is a limit. The public's interest in this matter is very deep. But it is not an economic one. They do not have the opportunity to make money as the result of contributing to the organization. So there is a limit to how much they can put in.

The practical result is that if my clients wanted to study this area, they would have to depend upon people who did not have the resources to gather the data directly because that requires real cash outlays (you have got to have the nets and the temperature devices and so forth) but people who might be able to volunteer some time off their work at a university to look at somebody else's data.

Of course, frequently the problems are that the data and gathering mechanisms are themselves subject to much question, particularly when you are dealing with something as sophisticated as the Atlantic Ocean and the Gulf of Maine, which is what we are talking about on this plant.

We have been one of the leading organizations, that is the New England coalition, in urging the Nuclear Regulatory Commission to provide financial assistance to all public groups that appeared before who have a need for that.

And that is now the subject of a study which is just being completed by a law firm here in Washington under contract with the Nuclear Regulatory Commission.

And as a result of that study, the Nuclear Regulatory Commission will issue some proposed rules. Either they will propose that they give no financial assistance or they will propose to give some under certain conditions. And there will be an opportunity for public comment.

I think the Nuclear Regulatory Commission is on the verge of becoming the first Federal agency to voluntarily do this. The Federal Trade Commission now provides for public funds to participants before it in regulatory matters. The Interstate Commerce Commission has an Office of Public Council that provides funds to lawyers to assist citizens in appearing before the agency's hearing examiners in conjunction with the Northeast Railway Organization. But with the exception of those two, and a policy in the Department of Defense to give funds to losing contractors on contract negotiations to encourage them to do subsequent bids (because bids take money) I know of no other Federal agencies which are now actively providing these funds. But the need for it is enormous.

And, in fact, the Senate voted such a provision as an amendment to the Energy Reorganization Act of 1974. But the then chairman, Chet Holifield, of the Government Operations Committee of the House, as one of his last acts in favor of nuclear power, struck it from the final bill.

But the pendency of that legislation triggered the current study by the Nuclear Regulatory Commission. If you are interested in the subject, I urge you to ask them to make available to you that study when it comes. It should be a fairly definitive study on the whole wisdom of Federal agencies providing funds to encourage the public to tell them their story and make a presentation to them.

Mr. Tobias. I noticed in the file that you handed to the subcommittee on the Seabrook proceeding a Freedom of Information Act request that you made of EPA region 1. In your dealings with EPA, have you been satisfied with EPA's handling of its public information obligations?

Mr. Roisman. If you mean it in terms of responding to the Freedom of Information Act request, no I have not. But in all candor that is the only one I have made to them, so far they are batting 1000. And I will not damn them for what I think will happen the next time.

Mr. Tobias. Thank you.

Senator Abourezk. Thank you very much for your testimony here today.

The hearing is adjourned.

[Whereupon, at 3:15 p.m., the committee recessed to reconvene, subject to the call of the Chair.]

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